A RATIONAL DRUG POLICY

- PROBLEMS
- PERSPECTIVE
- RECOMMENDATIONS

In the Interest of Social Justice in Health.

ALL INDIA DRUG ACTION NETWORK
AND
VOLUNTARY HEALTH
ASSOCIATION OF INDIA

20th March, 1986

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A lot of collective effort has been put in the production of this document to make information easily available to you. Acknowledgement of the direct and indirect source would be appreciated.

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§ DRUGS ARE CONSUMED BY THE PEOPLE

§ DRUGS AFFECT THE HEALTH OF THE PEOPLE

§ DRUGS ARE PAID FOR BY THE PEOPLE

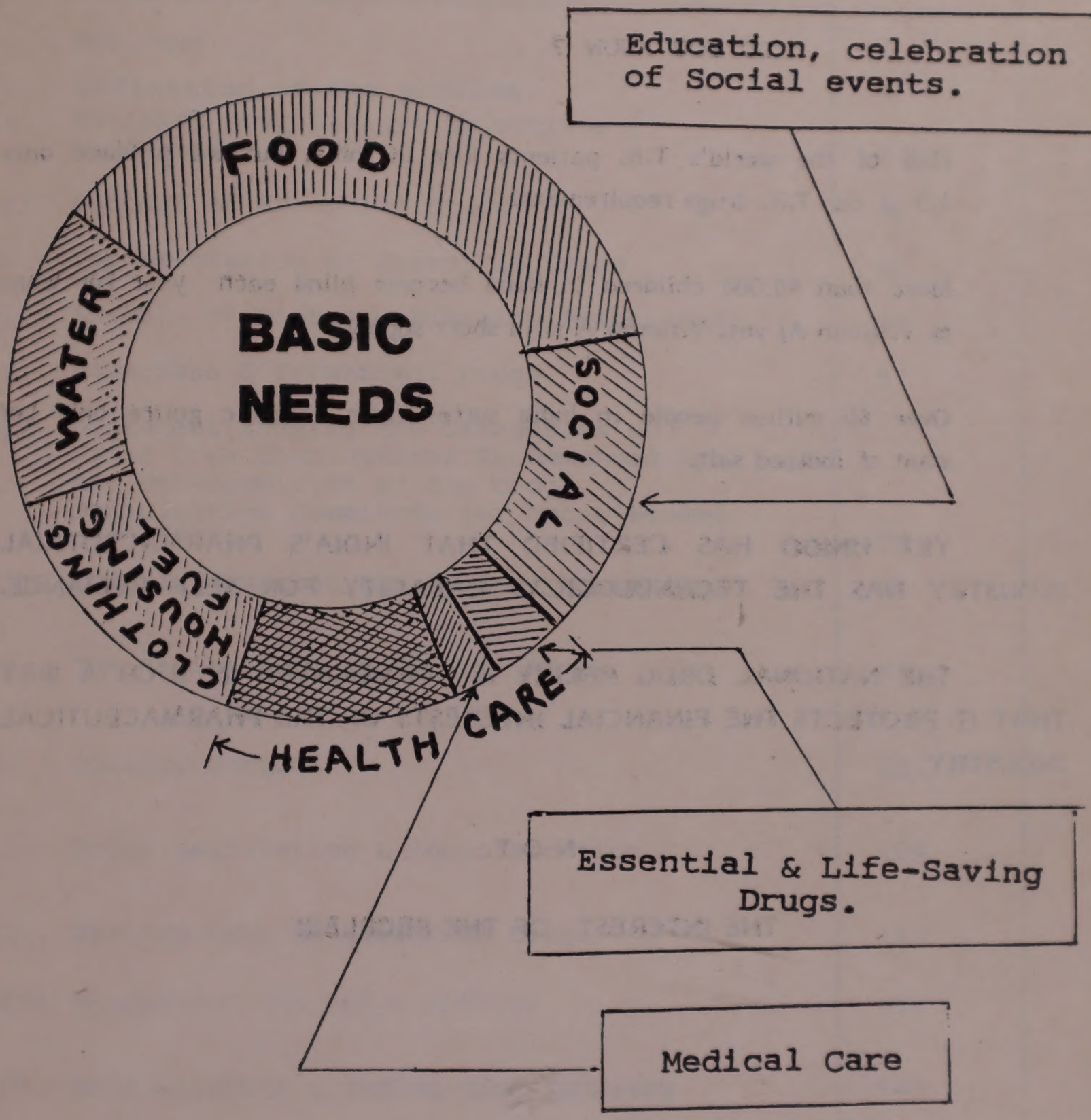
§ ESSENTIAL & LIFE-SAVING DRUGS ARE A RIGHT OF THE PEOPLE

"As between the lives of the citizens of this country on the one hand, and loss that may result to the manufacturers and traders by the immediate ban on the manufacture and sales on the other, the Government had chosen to view the latter as of more concern."

"It is the duty of the State to protect its citizens from injury and harm especially when the injury is not inevitable."

- Acting Chief Justice P. Subramanian Potti and Justice Paripuran, Kerala High Court, in their directive to the Union of India to release the list of brand names of banned drugs. Immediately ban the drugs recommended for banning & not to go on extending the cut off dates. 1982

NEEDS OF THE POOR MAJORITY



Role of Essential & Life-Saving Drugs are Minimal in the Life of Poor Millions, Ever This Need is Not Fulfilled.

DO YOU KNOW ?

- Half of the world's T.B. patients live in India, but we produce only 1/3 of our T.B. drugs requirement.

- More than 40,000 children in India become blind each year for want of Vitamin A; yet, Vitamin A is in short supply.

- Over 60 million people in India suffer from endemic goitre only for want of iodized salt.

YET **UNIDO** HAS CERTIFIED THAT INDIA'S PHARMACEUTICAL INDUSTRY HAS THE TECHNOLOGICAL CAPACITY FOR SELF RELIANCE.

THE NATIONAL DRUG POLICY IS FORMULATED IN SUCH A WAY THAT IT PROTECTS THE FINANCIAL INTERESTS OF THE PHARMACEUTICAL INDUSTRY

N O T

THE INTEREST OF THE PEOPLE!!!

C O N T E N T S

PROLOGUE

There was a time when medicine was 'practised' by men and women who were concerned about the total well-being of their patients. Medicine was both an art as well as a science. Medical knowledge was blended with human concern. Today, however, medicine is merely "administered" to treat symptoms & Cure disease

Up to now, official policies have been concerned more with determining production targets and remunerative prices of drugs. The entire drug industry has been seen as a sector of economic development which needs to be made profitable; and from which revenue can be made to accrue to the national exchequer. In the determination of prices and production targets, drugs and pharmaceutical products have been considered on par with any other industrial product. It is not surprising, therefore, that the drug and pharmaceutical industry is the responsibility of the Ministry of Chemicals under the Industry Ministry rather than the responsibility of the Ministry of Health.

This commercialisation of health-related products has precluded the formulation of a drug policy from the perspective of the health needs of the people. In recent years, there has been a tremendous number of pharmaceutical products marketed - estimated at anywhere between 50,000 to 60,000 in India - without a proportionate improvement in the health situation of the people. Marketing of these products ignore the health needs of the people. Promotional activities have created a demand which is much greater than the actual needs.

As far back as 1975, the Hathi Commission appointed by the Government of India, recommended a rationalization of the drug policy of the Government. It drew up a list of 116 drugs which it considered essential for the health needs of the people.

The World Health Organisation has also formulated guidelines to assist member countries to draw up a list of essential drugs.

It has been estimated that barely 20 per cent of the medicines available in the market today are necessary to treat over 80% of the diseases prevailing. However, an anomalous situation created by irrational planning is the fact that essential drugs to treat major diseases such as T.B., Leprosy, Malaria, etc. are in short supply, whereas unnecessary products such as tonics and anti-diarrhoeals proliferate in the market.

It is high time that a rational drug policy is formulated primarily from the perspective of the health needs of the people, rather than in the interest of the economic health of the drug industry. Experience has already amply shown that successful marketing of drugs and pharmaceuticals and the increasing profits of the industry has done nothing to improve the health status of the people : on the contrary, the vast majority of the people who live below the poverty line are further excluded from the benefits of health care of which they stand in desperate need.

This document attempts to focus attention on the main issues constituting the basic elements of a rational and comprehensive drug policy. It is addressed to policy framers, educators, representatives of the people in Parliament and in the State Assemblies, consumer education societies, social scientists and anyone who is concerned with social justice in the area of health care.

The perspective of this presentation is that of the common citizen who desperately needs the services of the health and medical establishments, but who finds these services receding beyond his capacity to pay.

In presenting our point of view, we make no attempt to conceal our bias. We believe that this point of view has never been presented systematically or forcefully enough to be considered by policy makers and those whose decisions vitally affect the lives of the poor who remain unrepresented in the decision-making and policy-framing processes.

This contribution to the general debate is not by way of being controversial; rather, it seeks to be advocatory. It is our hope that the formulation of anational drug policy will be weighted in favour of the vast majority of the poor. The rich and the powerful have the means to make themselves heard. They have the necessary resources to lobby effectively to promote their own interests. The poor have neither the structures nor the voice to influence public policy. They only have the **right**.

I

DEFINITION OF THE PROBLEM

The WHO estimates that 80% of illnesses are preventable. Most illnesses arise out of lack of basic necessities such as clean drinking water and proper sanitation. In India, 1.5 million children die annually from diarrhoeal diseases because of polluted water. These deaths can be prevented. Even when a child is affected by diarrhoea, most often treatment with a simple oral rehydration solution is sufficient. There is no need of administering any drugs. In fact the Oral Rehydration Therapy has been claimed to be the biggest medical revolution in modern times.

India has a population of 80 crores 48% of its people are below the poverty line - meaning that they can barely afford 2 square meals per day making expenditure on costly medical care a luxury they cannot afford. Of the total expenditure of the Government on health, 20% is spent on drugs. 80% of the drugs available are from the private sector, and need to be purchased by the people from commercial sources. (See Table 1.1)

Private spending on health care constitutes 84% of the total expenditure on health care in India (See Table 1.2)

Poor purchasing power and poor availability through the poorly developed health services limits the accessibility of drugs to a small percentage of the people.

It is estimated that only 20% of our people have access to modern medicine. The per capita consumption of drugs in India is one of the lowest in the world as obvious from the following table . (Table 1.3)

Yet any increase in per capita consumption of drugs unless it is for the right drugs at the right time, at the right costs, with the right information is useless.
Increased consumption of irrational drugs to maintain the health of the industry is counter health. This wastage of scarce resources on hazardous and irrational drugs is something our nation and its people cannot afford. Allowing such a situation to continue is sanctioning exploitation in the name of science and modern medicine.

There are about 60,000 brands of drugs in the Indian market - most of which are competitive products of several drug companies.

According to medical literature and drug information available from drug regulatory authorities from other countries, the prices of medicines have been going up by leaps and bounds in spite of price control orders. In addition to this, most consumers are not sure of getting quality products because the rate of sub-standard and adulterated drugs is growing. Consumers are also paying heavily for promotion costs which include free samples, gifts (indistinguishable from bribes), expensive conferences and intensive advertising.

Over 50% of these drugs are sold over the counter to people recognised to be hazardous & irrational without medical prescriptions These drugs are fancifully packed and often do not have instructions for use. When instructions are available, they are usually in English which is a language unknown to the majority of the literate population. Only 23% of Indians are literate. In most cases, the literature is couched in highly technical mystifying medical jargon which is beyond the comprehension of ever highly educated English speaking people.

The present model of health care services developed in the colonial period is basically the western model.

According to National Health Policy Statement it is "an imported, inappropriate, top heavy, overcentralized, heavily curative in its approach, urban and elite oriented, costly and dependency creating".

The over dependence on drugs is not merely marginalising and systematically eroding the previously existing alternatives. many of which were holistic. low cost, locally available, indigenous which encouraged self reliance, but most of the drug consumption is for self limiting trivial health problems.

Local alternatives for these have existed and even today many of the are the most appropriate and safe. Unlike in other countries, in India several indigenously developed traditional health care systems like Ayurveda Siddha and Unani exist.

Around 60% people of our country still depend upon locally available traditional medicine.

Table 1.1

The relative shares in dollar value of Pharmaceuticals distributed through the private and public sector services expressed as a percentage of the total pharmaceuticals consumed in 37 Third World countries

Country	Percentage Share in Dollar value	
	Private Sector	Public Sector
1. Argentina	93.7	6.3
2. Pakistan	93.2	6.8
3. Thailand	92.0	8.0
4. Indonesia	91.3	8.7
5. Nepal	90.9	9.1
6. Paraguay	90.0	10.0
7. Phillipines	90.0	10.0
8. Bangladesh	87.7	12.2
9. Singapore	85.0	15.0
10. Belize	83.0	17.0
11. Brazil	80.0	20.0
12. Chile	80.0	20.0
13. India	80.0	20.0
14. Maldives	80.0	20.0
15. Uruguay	80.0	20.0
16. Trinidad and Tobago	78.0	22.0
17. Mexico	77.0	23.0
18. Barbados	76.0	24.0
19. Peru	75.0	25.0
20. Venezuela	74.0	26.0
21. Grenada	72.0	28.0
22. Saint Christopher-Nevis	71.0	29.0
23. Colombia	70.0	30.0
24. Costa Rica	70.0	30.0
25. St. Vincent and the Grenadines	64.0	36.0
26. Jamaica	60.0	40.0
27. Malasia	60.0	40.0
28. Sri Lanka	57.0	43.0
29. Antigua	53.0	47.0
30. Burma	51.6	48.4
31. Bolivia	50.0	50.0
32. Dominica	50.0	50.0
33. Montserrat	47.0	53.0
34. Tansania	45.0	55.0
35. Ethiopia	43.0	57.0
36. Saint Lucia	42.0	58.0
37. Guyana	35.0	65.0

Source: Balasubramaniam K. "The Pharmaceutical Sector in the Third World: A strategy for collective self-reliance" - a paper presented to an International Conference on "Third World: Development or Crisis?" organised by the Consumers' Association of Penang, Malaysia, 9-13 November 1984.

Annex 3.1

TABLE 1.2

PRIVATE HEALTH CARE SPENDING
SELECTED DEVELOPING COUNTRIES

Countries	Private spending as percentage of total
Afghanistan	88
Bangladesh	86
Botswana	16
Egypt	41
Ghana	72
Honduras	63
India	84
Pakistan	63
Philippines	79
South Korea	84
Sri Lanka	40
Sudan	41
Thailand	66

Source: Report of a WHO meeting on Drug Policies and Management Procurement and Financing of Essential Drugs, No.DAP/84.5

TABLE 1.3

CONSUMPTION OF DRUGS : 1982

Country	Rs. per capita
India Rural	6
India Overall	19
Indonesia	30
Pakistan	30
Philippines	55
Turkey	65
Egypt	70
Nigeria	70
Taiwan	120
Mexico	150
South Korea	210
Japan	1000

Source: National Drugs & Pharm Dev. Council Working Group Report, 1984.

II

NATIONAL DRUG POLICY : OBJECTIVES & GUIDELINES

A. OBJECTIVES OF A RATIONAL DRUG POLICY

The need to have a rational drug policy was recognized a long time ago. The All India Drug Action Network feels the objectives of a National Drug Policy should be :

1. The **ensure availability** of **safe, essential** and **quality drugs** in consonance with the health needs of the people, particularly those required for preventive and primary health care.
2. To **eliminate irrational, useless** and **hazardous drugs.**
3. To prepare a **graded essential** and **priority list of drugs** in keeping with the actual health needs of the people for different levels of health expertise and services available.
4. To make all drugs available at **low prices** tgo the people, particularly the essential and priority drugs.
5. To develop **self-reliance** in **drug technology.**
6. To foster and encourage the **growth of the Indian sector.**
7. To provide a **leadership** role to the **public sector.**
8. To aim at quick **self sufficiency** in the **output of drugs** with a view to **reducing** the quantum of **imports.**
9. To ensure **quality control** of all drugs.
10. To ensure a **drug monitoring** and **drug information** system for **health personnel** and **consumers.**
11. To abolish brand names and **introduce generic names** for all drugs with assured quality.
12. To establish a **national corporation for the distribution of drugs,** retailing of drugs through **fair price shops** and government's health infrastructure, to decrease the cost involving middle men.
13. Mechanism to ensure **ethical marketing and trade practices.**

14. To promote research and development for self reliance, particularly to promote R & D in accordance with the health needs of the Indian people.

15. To ensure smooth Centre-State relations and inter-department coordination for effective and relevant drug production, drug control and drug supply.

16. To provide comprehensive drug legislation and administrative support to deal effectively with and implement all the above aims and objectives.

B. RECOMMENDATIONS ON GUIDELINES FOR A NATIONAL DRUG POLICY

THE UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT also formulated guidelines on technology issues in the pharmaceutical sector in the developing countries (See Annexure 2.1).

THE NON-ALIGNED MOVEMENT has also addressed itself to the question of establishment of a sane pharmaceutical order in the context of the health of the peoples of the developing world. The non-aligned Heads of State adopted a Resolution at the Fifth Summit in Colombo in August 1976 (See Annexure 2.2).

This concern was reiterated at the Sixth Summit of the non-aliged Heads of State in Havana in 1979 (See Annexure 2.3 & 2.4).

THE WORLD HEALTH ORGANIZATION has also enumerated some principles on which to establish a national programme for essential drugs.

1. Adoption of a list of essential drugs is part of a national health policy. This implies that priority is given to achieving the widest possible coverage of the population with drugs of proven efficacy and safety,

in order to meet the needs for prevention and treatment of the most prevalent diseases.

2. Only those drugs for which adequate scientific data are available from controlled studies should be selected.

3. Each selected pharmaceutical product must meet adequate standards of qauality, including when necessary, bioavailability.

4. Concise, accurate and comprehensive drug information drawn from unbiased sources should accompany each list of essential drugs. (See Annexure 2.5).

HATHI COMMITTEE'S main recommendations way back in 1975 reflected as many of the above (See Annexure 2.6).

Aims and objectives of a rational drug policy are being given diagrammatically (See Annexure 2.7).

Annexure 2.1

GUIDELINES on technology issues in the PHARMACEUTICAL SECTOR in the developing countries

MAJOR ELEMENTS OF AN INTEGRATED PHARMACEUTICAL POLICY

68. An integrated policy on pharmaceuticals obviously calls for the appropriate combination of a number of interdependent elements in accordance with the specific conditions prevailing in a given country. It has been the experience of several countries that, when they embark on a new pharmaceutical policy, account is taken of only a few such elements. The neglect of others has in some cases led either to total failure or to only partial attainment of the original objectives set. It is for that reason that this chapter lists some of the major elements that should be reflected in an integrated pharmaceutical policy for a given country. It goes without saying that the fact that these elements are interdependent does not imply that they must necessarily be combined in the same way. A brief description of each element suggests the type of options that a country may wish to consider in its policy package.

A. Limiting the number of similar medicines

69. The average doctor has a repertoire of perhaps 30-40 drugs prescribed regularly and another 50 or so used occasionally. There is no evidence that the use of a large number of drugs improves health care. On the contrary, it is known to increase the incidence of unwanted effects. Yet in the vast majority of countries many thousands of drugs are used containing up to 1,000 active ingredients (i.e. different chemical entities). The same chemical entity or mixture of entities is usually sold under several trade names. Thus it has been estimated that for 700 drugs there exist 20,000 names.[43] This profusion of medicaments is the result of treating drugs like other manufactured goods and of applying to them the principle of the market place.

70. Regulatory authorities usually ban only those drugs that are potentially dangerous, and recently, in some countries, drugs not shown to be effective for their stated purpose. Drugs that are less effective or slightly more toxic than already available drugs are nearly always allowed to be sold.

71. Moreover, the regulatory authorities may face problems when attempting to evaluate the literature on adverse reactions to drugs. For example, the editor of *Side Effects of Drugs Annual* (Amsterdam, Netherlands) has stated that he is obliged to maintain a black list of authors whose data he can no longer use since they lend their names to papers compiled or re-edited within the promotional departments of pharmaceutical companies.[44]

72. The availability of so many different drugs, and the use of similar names for different drugs, or of different names for similar drugs, entails dangers for public health as well as a tremendous waste of effort and money. From the public health standpoint, it creates and/or increases the chances of error in the prescription or absorption of drugs, and results in the inadequate treatment of patients and an increased incidence of adverse effects.

73. The abundance of medicines, furthermore, taxes both the memory and the working capacities of the personnel in charge of the distribution and control of the use of medicines. Again, the availability of more than one medicament for a given purpose increases the cost of imports, manufacture, formulation, packaging, storing and distribution. Small quantities of a large number of items are more expensive to handle than large quantities of a few items. The existence of brands sold under trade names adds to the supply costs.

74. In the light of experience in both developed and developing countries, it is now generally accepted that the number of drugs necessary for treating the large majority of diseases is relatively small. Only drugs that are necessary or useful for the treatment of identified health problems should be allowed to be sold. The number of available medicines should thus be limited in rich and poor countries alike, not only for budgetary reasons but also for the protection of health against inappropriate medication.

B. Essential drugs

1. Identification of essential drugs

75. The small number of drugs which suffice for almost all health needs, and which may be called essential drugs, must be identified and listed. For each therapeutic, prophylactic or diagnostic purpose, several drugs are now available on the world market. The choice of the essential drug from among those available should be made on the grounds of a good benefit/risk ratio and the best value of money. In some cases, availability precludes the choice of what is otherwise the best drug. Disease patterns vary greatly between countries, and the drugs that are essential will consequently differ.

2. Model list of essential drugs

76. Although the drugs essential for different countries are not necessarily the same, WHO has shown that it is possible to produce a list of the great majority of drugs essential in different countries.[47] Because of the

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[43] United States Federal Trade Commission, Bureau of Consumer Protection, *Drug product selection: Staff report to the Federal trade Commission* (Washington D.C., January 1979), p. 29.

[44] *The Lancet* (London), 29 September 1979, p. 696.

[47] WHO, *The selection of essential drugs* (Geneva, 1979), Technical Report Series No. 641, p. 9.

modifications required for individual countries, it is a model list, proposed as a core and guideline for the preparation of national lists.

3. National lists of essential drugs

77. Ideally, a national list should be prepared from the WHO model list by omitting drugs deemed not essential in the country and adding those required by the prevalence of particular health problems. Since health problems tend to transcend national boundaries within a region, the essential drug lists of neighbouring countries could in principe be the same or similar. In practice, physicians and other health workers will influence the choice of additions and deletions, depending on the nature and place of their training, their experience and cultural traditions, and promotional pressures from drug manufacturers.

78. An alternative method of preparing a national drug list is to take the list of all drugs currently available in a country and contract it by eliminating unnecessary or expensive duplications, or drugs for whose efficacy inadequate evidence is available. This has been tried in some countries, but has been less successful in reducing the number of drugs available.

79. For the establishment of a national list of essential drugs, the WHO Expert Committee on the Selection of Essential Drugs suggests that each country should appoint a committee comprising not only specialists in clinical medicine and pharmacology but also general practitioners and other health workers.[*] The advice of pharmacists is especially valuable on dosage forms, packaging and distribution problems. The national drug list should be reviewed every two or three years and a new drug should be introduced only if it offers a distinct advantage.

4. Sub-lists of essential drugs for different levels of use

80. Each national drug committee will have to establish sub-lists for use at different levels of health care. One such sub-list would include medicines that can be sold without prescription and distributed commercially. A second would include all medicines than can be prescribed by health workers other than doctors. A third would include all drugs reserved for use in general hospitals, and a fourth those for use in highly specialized hospitals. Thus practising physicians would be able to prescribe all drugs except those in the last sub-list.

81. The first sub-list of drugs, to be sold without prescription, would consist of 10 per cent or less of essential drugs and comprise mainly drugs for symptomatic and prophylactic use.

82. The sub-list of drugs for highly specialized hospital use should be kept as short as possible to ensure that the use of the drugs concerned remains genuinely restricted to conditions specifically requiring them, and physicians are trained to respect these restrictions.

[*] WHO, *The selection of essential drugs* (Geneva, 1977), Technical Report Series No. 615, p. 11.

5. Sub-list of vital drugs

83. Certain drugs must be constantly available to patients who need them in order to maintain life and reasonable health, for example insulin, digoxin, penicillin, antimalarials. The delivery of such vital drugs to and within a country must never be interrupted, and they must therefore be supplied preferentially. They must be available to the poor as well as to those who can pay for them.

6. Enforcement of the exclusive use of essential drugs

84. Although it is easy to enforce the exclusive use of essential drugs in the public sector, this has not been generally attempted in countries with a private pharmaceutical sector. Unless essential drugs are used in the private as well as in the public sector, an essential drug policy will not succeed.

7. Information sheets on essential drugs

85. Essential drugs must be accompanied by adequate information required for their safe and effective use. Model information sheets for all the drugs on the WHO model list are being prepared by WHO according to a standard format. These can be easily translated into any language and can be used to assemble a local formulary. The use of these information sheets will therefore make it unnecessary to rely on whatever information material may be provided by manufacturers.

8. Information sheets on use of drugs in the prevention and treatment of prevalent health problems

86. Health workers at all levels need clear and concise information on the management of prevalent health problems. This can be provided according to the same principles for all health workers, but village health workers, for example, with summary training, will need less detailed information than medical assistants in a health centre. For each problem, an information sheet should state: (*a*) how problems will be identified, (*b*) the possible actions with their rationale, and (*c*) the expected outcome and the follow-up that may be needed. Therapeutic guidelines have already been produced for many health problems, for example by the WHO task forces on various communicable diseases, and these guidelines could form the basis of therapeutic information sheets for health workers.

C. Regulation of drug promotion

1. Use of generic names

87. Skilful brand name promotion has been one of the significant sources of the market power of the pharmaceutical industry. The creation of brand loyalty bestows on the original manufacturer a monopoly power which continues long after the patent protection has expired and competitors have entered the field. As a result, patients do not benefit from cheaper generic equivalents.

88. Brand names also tend to confuse prescribers in selecting therapeutic drugs. Non-proprietary names, on

the other hand, help them to think more clearly about drugs. However, the drug industry conditions doctors so effectively that they often identify a drug only by its brand name.[29]

89. Non-proprietary names have the advantage of ensuring recognition of the identity of prescribed drugs. For example, the generic names hydrochlorothiazide, polythiazide and cyclopenthiazide indicate that they are thiazides, whereas their respective brand names "Esidrex", "Renese" and "Navidrex" give no such indication. Similarly, the generic names ampicillin, cloxacillin and carbenicillin indicate that they are penicillins, whereas their respective brand names "Penbritin", "Orbenin" and "Pyopen" do not.

90. Another source of confusion is the existence of so many brand names for a single drug that it becomes impossible for a doctor to remember or even to recognize them all. In Sri Lanka, tetracycline was sold under more than 20 different brand names such as "Achromycin", "Glocycline", "Tatracyn", "Polfamycin" "Scancycline", "Imperacin", "Probacycline", "Diocycline", "Hostacycline", "Tetrarco" and "Ambramycin". Some practitioners have unwittingly switched from one brand name to another in the mistaken belief that they were prescribing different drugs.[30]

91. Brand name prescribing can lead to dangerous consequences, since many drugs with quite different actions and uses have similar brand names. Many of these drugs are available over the counter in many developing countries, further increasing the risks and dangers. Another disadvantage is that patients are inconvenienced by searching for a prescribed brand from pharmacy to pharmacy when alternative brands are available. This would be obviated by the use of non-proprietary names. Moreover, although medical journals refer to drugs by their non-proprietary names, this information cannot be used in practice unless doctors are aware of those names.

92. Doctors often resist generic prescribing because the brand names are more familiar and tend to be easier to remember. The pharmaceutical industry's main argument agains generic prescribing is that the brand name guarantees the quality of the product, since a large and reputable company would be less likely to market substandard drugs. But brand names do not ensure quality. The United States Food and Drug Administration has shown that branded and generic products have been substandard with about equal frequency.[31] A non-branded product from a reliable firm is as likely to be effective as a branded product.[32]

93. Generic equivalents are usually much cheaper than the corresponding branded drugs. For example, the Drug Benefit Formulary No. 13 of the Ministry of Health, Ontario, Canada, effective 1 July 1980, indicates that generic diazepam is 10 times cheaper than the branded equivalent "Valium".[33]

2. Enforcing the use of generic names

94. The simplest solution to the problems outlined in the preceding section is to forbid the use of brand names. In some countries, however, this may not be practicable, and an alternative is to require the use of generic names together with that of brand names. Regulations could be issued requiring the generic name to be printed on all labels and promotional material more prominently and/or in larger type than the brand name, and preceding it.

95. It is essential to have a reliable system of quality control or assurance if generic names are to be established in place of brand names. An attempt to introduce generic names without adequate quality assurance has sometimes failed, as in Pakistan, because interested parties can adduce the poor quality of certain non-proprietary preparations as a strong point against such a policy.[34]

3. Information on drugs other than those on the essential drug list

96. Countries that import branded medicines need to control their promotion, which includes checking all information provided by the manufacturer and his agents. This is necessary because excessive and inappropriate promotion leads to excessive and inappropriate use, which wastes scarce resources and harms the population.

97. The first requirement is a licensing system for medicines, under which only drugs that are acceptable, safe and effective are allowed to be sold.[35] The licensee must specify the uses of the preparation, with any restrictions, warnings, etc. limiting its use. These conditions can be summarized on a data sheet, as is the practice, for example, in the United Kingdom. All promotional statements made by the manufacturer must be concordant with the data sheet which forms part of the licence. This requirement places responsibility for compliance on the manufacturer.

98. It is in theory more effective, but much more laborious and expensive, to require promotional material to be submitted for official approval before it is used. The simplest solution would be to prohibit all promotion. If this is to be done, the government authority must take complete responsibility for the provision of adequate information on all the medicines sold, including essential drugs. As in the case of essential drugs, the type and amount of information required will differ for different uses. Doctors will need more information than non-medical prescribers, and these will need more than consumers. Separate sets of informa-

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[29] See for example "Case studies in transfer of technology: pharmaceutical policies in Sri Lanka" (TD/B/C.6/21), para. 44.

[30] *Ibid.*, para. 46.

[31] H. E. Simmons, "Assuring total drug quality", *Journal of the American Pharmaceutical Association* (Washington D.C.), vol. NS 13, No. 1, January 1973, p. 96.

[32] T. D. Whittet, "Formulation and drug action", *Prescribers' Journal* (London), vol. 11, No. 2, April 1971, p. 48.

[33] Canada, Ministry of Health, Ontario, *Drug Benefit Formulary: Parcost Comparative Drug Index* (Ontario, 1980), No. 13, p. 44.

[34] J. S. Yudkin, "Pharmaceutical industry: golden goose or curate's egg?", *World Medicine* (London), vol. 15, No. 4, 17 November 1979.

[35] International Research Group for Drug Legislation and Programs, *Pharmaceuticals and health policy*, R. Blum and others eds. (London, Croom Helm, 1981), p. 241, sect. 9.3.

tion for at least these three groups will therefore be needed for many medicines.

D. Educating physicians, health workers and consumers

99. Whenever restricted lists of essential drugs are introduced, two main objections are raised by doctors. The first is that the drugs which the doctor regards as essential for the patient have not been so assessed by the competent national authorities, and he considers that his clinical freedom has been encroached upon. The second objection, which is more often raised, is that he will no longer be able to use the familiar and trusted trade names and that there may be no way of telling whether the generic product is therapeutically equivalent to the brand name drug. Objective information needs to be provided to respond to these objections.

100. Health workers need training in recognizing the merits of a restricted list of drugs. A system of information thus forms a vital part of a national drug policy.

101. Appropriate background education in pharmacology and drug therapy is therefore of the utmost importance for all concerned with the prescribing and provision of medicines. This education should be continuous.

102. Medical school teaching should include a much more thorough grounding in clinical pharmacology and therapeutics than has hitherto been the case. The concepts and practical aspects of the use of essential drugs must become ingrained in all medical graduates. Practising doctors need postgraduate education to achieve the same understanding and proficiency. This could be provided by short courses and reinforced by regular publications such as *The Prescriber's Journal* or *The Drug and Therapeutics Bulletin*. Doctors must also take a major responsibility in the education of other health workers in their area. This will reinforce their own continuing education and will promote the harmonious and effective use of medicines in the health service. They should also take every opportunity to educate the public in the proper use of medicines.

103. Educational programmes both in schools and for adults should include material on the most common illnesses and their treatment. At the same time, people should be taught not to place excessive reliance on medicines. The importance of prevention, and each individual's role in it, must be understood. The prevalent belief that there is a pill or an injection for every ailment must be shown up as the myth it is. Consumers must be equipped to understand the simple directions to be followed in using medicines effectively and safely.

E. Assessment of drug utilization

104. The supply and distribution of essential drugs together with the requisite information will not of itself ensure their optimal use. Much can happen to frustrate the intentions and plans of health authorities. These authorities therefore need to know how essential drugs and also others are being used by health workers and by the public. Detailed information is difficult and expensive to obtain, because it will usually require surveys by specially trained staff. However, some estimates of utilization can be made from the sales or issue figures for individual drugs of the central and regional medical stores and from the sales figures of importers and wholesalers. These figures can be expressed in terms of the number of courses of treatment that they represent. Doctors and other health workers in different areas can be asked to estimate how many cases of the relevant health problem or problems they see every week or month. A comparison of the issue figures with the estimated incidence of the condition treated will show whether they correspond or are discrepant, i.e. whether there seems to be overtreatment or undertreatment. Suspicion of either, if it is serious, calls for specific further investigation. If undertreatment or overtreatment or other inappropriate use of medicines is confirmed, remedial education and information must be directed to the health workers concerned. It is only by such constant vigilance that misuses and misunderstandings concerning drugs can be promptly corrected.

F. Drug procurement

1. Centralized bulk purchase under generic names

105. The procurement of drugs (and of raw materials and chemical intermediates) of the appropriate quality at as low a price as possible is most important for achieving optimal utilization of economic resources and, in the case of imported drugs, maximizing the use of foreign exchange resources. Many developing countries, faced with a serious foreign exchange drain to developed countries in payment of imports of pharmaceuticals, have therefore recently begun to look for appropriate means of scaling down the cost of accelerating imports, improving their import operations and procuring methods and enhancing their bargaining position.

106. The total drug purchases of individual developing countries are usually very small compared with the world-wide sales of the large drug companies. The bargaining power of those countries is therefore not very strong, and it is further reduced when the total imports of a country are distributed among several importers and/or when one drug is purchased in a number of brand forms.

107. Experience in developing countries has shown that an immediate and dramatic improvement is possible by rationalizing the availability of drugs and the method of purchase. The Sri Lankan experience, for example, demonstrates effectively that in a developing country a centralized drug purchasing agency, using a national formulary comprising a restricted list of essential drugs, is a viable and powerful instrument for saving foreign exchange, rationalizing drug usage and supplying essential drugs at a reasonable price to the whole country.[14]

108. The centralized purchase of drugs limited to a national list of drugs, in addition to rationalizing purchasing procedures, would also help to rationalize storage, distribution, prescription, quality control and

[14] "Cases studies in the transfer of technology: pharmaceutical policies in Sri Lanka" (TD/B/C.6/21), para. xvi.

the provision of objective information on drugs to health workers. The prerequisites for centralized purchasing are a restricted list of drugs and the exclusive use of generic names. It will then be necessary to work out estimates of the quantities required annually or biannually. Ideally, estimates of items and quantities should be based on the health information available. However, in many developing countries this cannot be done in the initial phases owing to lack of adequate health information. Estimates may therefore have to be based on actual demand, taking into consideration previous years' consumption. These estimates can be re-evaluated and corrected through inventory control and drug utilization surveys.

109. A centralized purchasing system could be established in every developing country, whatever its level of development. In nearly all developing countries, health care is delivered by both the public and private sectors. Centralized procurement may therefore initially have to be for public sector requirements only. After a period of time, when the system functions well, it could extend its operations to cover private sector requirements as well.

110. To maximize its bargaining power, the purchasing agency should build up a market intelligence unit. It could start by collecting and recording the following information:

(*a*) Producers and their manufacturing practices and production scale;

(*b*) Price trends;

(*c*) Previous performance of suppliers regarding quality, price and service;

(*d*) Data on new drugs, especially registration status in the country of origin and/or selected developed countries (to avoid the rigorous registration rules in developed countries, certain firms manufacture their new drugs in their subsidiaries in developing countries);

(*e*) List of addresses and manufacturing practices of firms producing generic drugs.

111. The total drug requirements of a number of small developing countries are too small for them to take advantage of economies of scale merely by centralizing the procurement system. A way of resolving the problem would be for such countries in the same region to pool their drug purchases. The first of such regional centres is to be established by the countries of the Caribbean region.[11]

2. Purchasing methods

112. The vast majority of essential drugs are well established multisource drugs. These could be purchased by world-wide tendering. In the case of drugs for which bioavailability poses problems, restricted quotations could be called for from a limited number of selected manufacturers.

113. The mechanism to be used for international tendering may be summarized as follows:

(*a*) The list of drugs to be procured, with relevant information, to be advertised in the press;

(*b*) Tender specifications to be sent to foreign diplomatic missions in the country concerned as well as to the country's diplomatic missions abroad;

(*c*) The list to be sent direct to generic suppliers to ensure their participation in competitive bidding;

(*d*) Tender offers received within the deadline to be processed and evaluated by a purchasing committee, which would choose the cheapest supplier subject to quality assurance.

3. International co-operation

114. There is a need for United Nations agencies to pool their efforts in assisting developing countries in:

(*a*) Establishing an information system on drug prices and pricing systems, drug management, drug evaluation, price of raw materials, packaging, etc.;

(*b*) Establishing collective procurement centres on a regional basis;

(*c*) Disseminating information on the procurement system of international agencies (e.g. UNICEF) so that developing countries may benefit from the experience of these agencies;

(*d*) Establishing and strengthening national procurement agencies.

G. Quality assurance

1. Drug control regulation

115. Production of drugs of assured quality and maintenance of that quality while the drugs move along the various distribution channels until they reach the patient are the responsibility of the producers and distributors (both wholesale and retail), exercised in the framework of regulatory controls formulated by Governments on a legal basis. Drug control regulations vary from very rigid sets of rules well implemented in developed countries to regulations poorly implemented in some developing countries and virtually no controls in some of the least developed countries. While some pre-market screening is carried out in many developing countries, there is virtually no post-market surveillance, and control of business practices is lax, reflecting the limited financial, technological and human resources of those countries. Under these conditions, there is no mechanism to prevent unscrupulous "dumping" of any drug in a country. Hence efforts should be made at both national and regional levels to ensure that only safe, effective and inexpensive drugs are marketed in a country.

2. Action at the national level

116. In view of the constraints described earlier, the following may be considered as priority areas requiring suitable legislation in countries where quality assurance of drugs is a weak component of the pharmaceutical supply system:

(*a*) Selection of a list of essential drugs for the country;

(*b*) Use of generic names whenever possible;

(*c*) Registration of drugs limited to the list prepared and based on technical information from neighbouring

[11] See footnote 6 above.

countries, regional organizations or international agencies (e.g. WHO);

(*d*) Imports, local production and distribution limited to drugs registered in the country;

(*e*) Ideally, all imports to be channelled through a State purchasing agency so that quality assurance can be built into the purchasing procedure; the possibility of substandard drugs entering the market will therefore not arise;

(*f*) Effective use of the WHO certification scheme;[18] it should be noted that by 1980 only about 40 developing countries had joined this scheme;

(*g*) Control of marketing practices such as advertising, information on and promotion of drugs;

(*h*) Control of labelling of products and surveillance of marketed products;

(*i*) Exchange of information among countries on pharmaceutical inspection;

(*j*) Development of basic tests for the analysis of the most essential drugs;

(*k*) Inspection of manufacturing establishments, stores and pharmacies;

(*l*) Regulations on multisource international procurement;

(*m*) Legal definition of drug distribution system at the central, regional and peripheral levels.

117. If suitable legislation were enacted to implement the measures listed above, the drug control authority of a country could function optimally with minimum resources. Moreover, developing countries could also pursue certain other strategies to minimize the resources required.

3. Subregional and regional co-operation

118. Small countries with inadequate resources to establish fully equipped quality control laboratories could establish regional quality control laboratories to supplement the work of the national laboratories. The regional laboratory could develop certain basic analytical procedures that could be carried out in the national laboratories. The more sophisticated analyses could be carried out by the regional laboratory. It is relevant to note that the reason why many developing countries are obliged to purchase the more expensive branded products from traditional sources is their inability to ensure the quality of drugs bought openly on a competitive world market. The investment in such regional drug laboratories would be repaid over a period of a few years once drugs were bought on the world market at a reduced cost. A minimum saving of 30 per cent, but sometimes of as much 50 per cent, could be made by centralized bulk purchase.[19]

H. Drug distribution

119. It has been estimated that from 50 per cent to 80 per cent of the population in developing countries have no regular access to pharmaceuticals or to a health care delivery system. One of the main causes is the lack of distribution channels reaching the periphery. It is therefore essential to devise a system of distribution that will cover even the most remote areas.

120. Many developing countries are successfully experimenting with a multitier system involving the use of trained paramedical personnel at the periphery, general physicians and specialists, and district and central hospitals. At the remotest delivery point there would be a community health worker, selected by the community and trained at the district hospital in health education, elements of first aid, symptomatic diagnosis of minor illnesses and drug administration for these illnesses. The formulary committee could prepare a list of a few basic drugs for use by these workers together with an information manual on storage, use and precautions to be taken during administration. At the next level would be health workers or health assistants who have received formal training and who act as a link between the community health worker and the district hospital. They would use a larger list of drugs, including vaccines for immunization. Health education and preventive medicine would be their principal responsibility.

121. The question of self-medication also needs to be explored to increase the availability, at the remotest periphery, of a limited number of pharmaceuticals with a wide margin of safety that could be classified as household remedies. These could include drugs used in the treatment of: (*a*) minor ailments such as fever with aches and pains, usually viral in origin, and coughs and colds; (*b*) easily diagnosable parasitic diseases in areas where these are endemic (e.g. malaria, roundworm, tapeworm). To this list could be added oral rehydration salts for infants and young children with diarrhoea.

122. It would be helpful to establish a distribution network covering central, regional, subregional and peripheral areas, with activities as follows:

Central store

Activities:

Procures and stores the drugs required for the country;

Distributes drugs to the regional stores;

Distributes drugs to health institutions and pharmacies in the localities.

Staff:

Pharmacists;

Personnel trained in stock control and management.

Regional store: Receives drugs from the central store or direct from suppliers with the approval of the central procurement agency.

Activities:

Distributes drugs to subregional stores;

Distributes drugs to health institutions and dispensaries within a defined area.

Staff:

Pharmacist, assisted by paramedical personnel.

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[18] WHO, *Quality control of drugs: A. Good practices in manufacture B. Certification scheme for products moving in international commerce* (Geneva, 1977).

[19] "Case studies in the transfer of technology: pharmaceutical policies in Sri Lanka" (TD/B/C.6/21), table 2.

Subregional store

Activities:

Distributes drugs to:
Health centres and clinics;
Community health workers;
Rural dispensaries.

Staff:

Paramedical personnel.

123. At the peripheral level, dispensing could be handled by community health workers; the list of drugs is defined and the health worker is trained in storage, accounting and dispensing methods.

I. Regulation of drug prices

124. Some form of product and price regulation for pharmaceuticals is necessary to provide for consumer protection, ensure supplies at a "fair" price, generate greater emphasis on the production and supply of essential drugs, and protect the local industry from unfair competition resulting from the practices of transnational companies and from international market trends.

125. From an early stage of the development of a national pharmaceutical industry, developing countries should initiate a system of registration of drugs that may be produced and marketed in the country. Through this mechanism, emphasis can be placed on essential drugs and their formulations, while drugs of doubtful value, or with only marginal benefit over existing and well-established drugs, can be excluded. To direct the development of the pharmaceutical industry effectively, it would be useful to introduce a system of licensing of production. In this way the development of the industry could be planned and its growth suitably monitored. In issuing licences, the emphasis should be on the production of essential drugs, particularly those of large volume; production of simpler formulations and household remedies should be reserved for local industry. Production licences for transnational enterprises should preferably be issued in the context of joint ventures with local entrepreneurs and should include a phased programme of basic production with backward integration.

126. The pharmaceutical industry is highly competitive, and local industry in developing countries when pitted against international market competition is bound to suffer. This is due to many factors, such as the advantage of large volumes of production in developed countries, the overall technological superiority of those countries, and the fact that they have easy and cheaper access to raw materials. For the development of a local pharmaceutical industry, particularly of bulk drugs, it would therefore be necessary to provide for some form of protection. The various mechanisms for such protection could be: (*a*) high tariffs on imports of finished goods; (*b*) lower or no tariffs on imports of raw materials; (*c*) authorization of imports only of essential drugs that are not produced locally.

127. To generate local production of essential drugs, it might be necessary to offer special incentives to producers, since the profit margins are relatively low. Such incentives could be in the form of: (*a*) special tax relief; (*b*) liberal quotas for imports or for increased formulation capacity, so that entrepreneurs would consider it remunerative to take up the production of essential drugs; (*c*) credit on easy terms, such as lower interest rates and more ample financing.

128. Drugs fulfil a social need, and in developing countries they are needed most by the lowest income groups. Hence their prices should be kept as low as possible. In practice, however, the drug industry has been in general among those with the highest profit margins. To prevent this exploitation of an essential human need, some form of price control is necessary; however, while providing for consumer protection, price control should not be so stringent as to hinder the growth of the industry. Two of the many forms of price control are as follows:

(*a*) The total profit of the drug industry units can be fixed at a certain level, which would vary from country to country (a 12-15 per cent post-tax profit on total turnover is normally considered adequate for the formulation industry and 15-18 per cent for the bulk drug industry);

(*b*) A cost analysis of each product is carried out and a certain mark-up is allowed on the ex-factory cost (a mark-up of 75-100 per cent is considered adequate).

129. To ensure that essential drugs are available at a lower price, selective mark-ups may be considered under this system: a lower mark-up for essential drugs and higher mark-up for others. Special incentives could also be offered to producers of essential drugs.

J. Industrial property system

130. Policies on patents and trade marks in the pharmaceutical sector vary from country to country, reflecting differences in the degree of local manufacture, the participation of foreign subsidiaries and domestic firms and the procurement policies applied by the public sector. Nevertheless, some general suggestions may be put forward on the basis of which specific policies can be developed.

1. Patents

131. In those developing countries in which patent protection is still given to pharmaceutical products, it is important to withdraw such protection from the patent legislation. When patents are not granted for pharmaceutical products, local firms are able to import the products from the most convenient sources on the world market or to manufacture them, following a different method, without licensing agreements with the patent owners.

132. An alternative to the exclusion of pharmaceutical products from patent protection is to reduce the duration of pharmaceutical patents, as has been done for example in Costa Rica or India, and/or to have an expeditious system of compulsory licensing, such as that applied in the Philippines. In developing countries in which patent protection is given to processes, it is very important to ensure that such protection is not extended to products, and that "product by process" protection is not applicable. In this connection, the deletion of article 5 *quater* of the Paris Convention that has been

requested by developing countries in the ongoing revision of the Paris Convention is particularly relevant.[60]

133. The issue of not granting patent protection to processes of production is particularly important for countries which are considering the local manufacture of active components.

134. In addition to the form of patent protection, other issues are worth considering in any change in patent legislation. These relate mainly to ensuring the satisfactory working of the patented invention through means such as an expeditious system of compulsory licensing, forfeiture or revocation; shortening of the duration of the patent, and to the question of the burden of proof in case of infringement.[61]

2. Trade marks

135. The success of a policy aimed at shifting from trade marks to generic names in the pharmaceutical industry depends very much on the means used to convince the different categories concerned with the industry of its viability. While consumers would clearly be the main beneficiaries of such a policy, since they would obtain similar products at lower prices, the co-operation of manufacturers, doctors and pharmacists would also have to be secured.

136. Although manufacturers, both foreign and domestic, usually prefer to concentrate their marketing efforts on the more lucrative sections of the market, where brand proliferation predominates, the emergence of a two-tier operational structure in the pharmaceutical industry may be noted, involving (*a*) specialist innovative supply and (*b*) broad-line generic supply.[62] The existence of such a structure should make it easier to secure the participation of manufacturers in the proposed policy.

137. In countries where the medical services are in the public sector, medical practitioners could be asked to favour the cheaper substitutes. Such a policy could also apply where doctors themselves practise in the private sector but where medical insurance expenditure is State financed through public sector agencies. Financial incentives could also be suggested.

138. Pharmacists are not necessarily committed to brand competition. Their capital requirements for stocking the range of brands of a particular product may be substantial. Their preference for higher priced brands is due mainly to the fact that their earnings are proportionate to the sales value. This could be changed by linking their earnings to the number of prescriptions dispensed.

139. All these factors should be taken into account to ensure a successful policy in this area.[63]

140. In addition to the main factors that should be taken into account in a policy aimed at shifting from trade marks to generic names in the pharmaceutical sector, two other issues related to trade marks deserve close examination.

141. First, the whole policy of granting protection to trade marks and trade names should be changed. While it would seem important to ensure the protection of trade names in order to identify the source of the products concerned, a policy aimed at cancelling the protection of trade marks that are no longer used in a country would clearly be advisable. This could be combined with a restrictive policy of granting new trade marks only to new products in respect of which the health authorities consider it advisable that both trade marks and generic names should be used.

142. Secondly, transfer of technology agreements in which foreign-owned trade marks are licensed to domestic firms should be regulated. The possibilities of joint use of a foreign and a domestic trade mark for a limited period should be examined.[64]

K. Technology plan for the production of pharmaceuticals

143. The two major elements in a technology plan are: (*a*) phasing of production depending upon the technological level of the country and its R and D capabilities; (*b*) development of the institutional infrastructure required to assimilate, adapt and improve upon imported technology and generate more technology suited to local resources. The plan has thus to be such as to help to reduce dependence on foreign technology and gradually establish a self-reliant technology base.

144. The setting up of a pharmaceutical industry generally takes place in several distinct steps, all of which do not have to be started simultaneously and at the same location. They should be suitably phased.[65] Even in small least developed countries, some elements of production can be carried out locally. The exact stage of production to start with and the rate of change from one phase to the other will vary from country to country, depending upon its technological level and the manpower available.

1. Packaging and formulation industry

145. Starting with a packaging industry for imported bulk formulated products, any country can quickly start production of simple formulations such as tablets, capsules, ointments and syrups,[66] which are relatively easy to produce. A fair-sized plant for the production of pharmaceuticals to serve a population of 1-2 million[67] would need an investment of the order of

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[60] See para. 59 and footnote 41 above.

[61] These policy changes are to be analysed in a forthcoming study by the UNCTAD secretariat, "The impact of new policies and legislation in the field of industrial property".

[62] CTC, *Transnational corporations and the pharmaceutical industry* (*op. cit.*), paras. 272-274.

[63] These questions are discussed on the basis of the available evidence for some countries in a report by the UNCTAD secretariat entitled "Trade marks and generic names of pharmaceuticals and consumer protection" (TD/B/C.6/AC.5/4).

[64] For a thorough discussion of the problems relating to the licensing of foreign-owned trade marks, see *The role of trade marks in developing countries* (*op. cit.*), paras. 147-171 and 288-300.

[65] "Technology policies and planning for the pharmaceutical sector..." (TD/B/C.6/56), p. 19, table.

[66] *Ibid.*, annex IV.

[67] Consumption would vary from country to country depending upon the incidence of disease, of the health services and the distribution system in the country.

$2 million (at 1980 prices) in machinery and equipment, a built-in area of about 35,000 sq ft (20,000 sq ft for main plant and 15,000 sq ft for quality control and R and D laboratories, stores and administration) and a personnel of about 250. The personnel would include about 30 supervisory staff (20 for plant, 5 for laboratory, 5 for maintenance), who would be graduates or postgraduates in pharmacy, science and engineering, some of them with practical experience in the plant of a reputed pharmaceutical company, about 200 skilled and unskilled workers, and 20 administrative staff.

146. A school of pharmacy should be established as early as possible with emphasis on pharmaceutical technology in its curriculum. Countries where such schools already exist should encourage them to set up pilot plants/semi-industrial scale units attached to the school to train students in production processes, and also arrange for the practical training of students and graduates in some of the factories in the country/subregion/region.

147. The technology for the setting up and running of such a plant could be acquired from other developing countries, for example, the Republic of Korea, Brazil, India and Cuba, whose experience would be more easily applicable to developing countries than that of highly developed countries. Some manufacturers in these countries have already set up plants in other developing countries as joint ventures with Governments/entrepreneurs. One way of proceeding would be to secure the services of a consultant from one of these countries, to assist, together with a design and engineering firm, in preparing a composite package proposal for the setting up of the plant, and supervise its construction. The interim period could be used to arrange for the training of the supervisory staff, with the assistance of the consultant. Another method would be to set up the plant as a joint venture with one of these countries. Various arrangements could be visualized, such as public sector/public sector, public sector/private sector, or private sector/private sector. The training of personnel must be an integral part of any such arrangement.

148. The choice of products to be manufactured in such a plant would be dictated by the needs of the country. Emphasis should be placed on the production of essential drugs, particularly those needed in large volume. A plant of the size suggested above could produce annually about 250 million tablets of different types, 25 million capsules, 500 kl of liquids and orals, and about 5 tons of ointments.

2. Production of transfusion solutions (large volume parenterals)

149. A second plant should be started for transfusion solutions. It could be added to the premises of the formulation plant described above or as a separate unit. It could even be established as a part of a hospital pharmacy. Since transfusion solutions are life-saving and thus of critical importance, it is vital for countries to become self-sufficient in their production. Moreover, high transport costs are entailed in imports of bottles of such solutions, owing to the large volume. A plant producing about 2,000 bottles/450 ml daily, which is considered a viable unit, would cost about $500,000 at existing prices of machinery and equipment and serve a population of 1-2 million.

150. Once these two plants are set up it should be possible to extend production to include other formulations and injectables. The training of personnel to perform sterility and pyrogenicity testing is of importance for this production. Innoculation rooms and animal houses would also have to be provided.

3. Bulk drug production

151. Production of bulk drugs and of some essential chemical intermediates should form an integral part of the development plan for the drug industry in every country. The production of some bulk drugs is not linked to the chemical industry, and can be profitably taken up by many developing countries. These drugs include biologicals such as those derived from slaughterhouse and hospital wastes, immunologicals (vaccines and sera) and antibiotics, phytochemicals and fermentation products. Most developing countries are agriculture-based, and these products are essentially dependent upon agricultural raw materials. Developing countries could therefore set up industrial units for one or more of these products. This could also take place in phases. For example, in the case of biologicals and plant products, crude extracts could be made first and exported to more advanced countries for final processing.

L. Regional and international co-operation

Establishment of norms on marketing, trade, distribution and transfer and development of technology relating to pharmaceuticals

152. It is of particular importance in this connection to explore the possibility of establishing an entirely new set of criteria or standards governing marketing, trade, distribution, access to technology and promotion of development of national technology in the pharmaceutical sector. There are several reasons for this.

153. To begin with, health is both a personal and a public good. Increasingly, public authorities are accepting full responsibility for the health of the population. However, implementing this policy has become particularly difficult in developing countries where often about one half of public expenditures on health has to be devoted to imported pharmaceuticals. It is obvious that government resources for improving the supply of health facilities to sectors of the population so far not covered are severely strained by such heavy concentration on pharmaceuticals. Secondly, and more concretely, programmes are now under way aimed at meeting the health requirements of all peoples before the century is over. Thirdly, a large part of the technological knowledge required for the manufacture of pharmaceuticals, particularly of essential drugs, is now in the public domain. Its successful use by developing countries hinges critically not so much on patent rights as on their capacity to unpackage foreign investment and thus to obtain supplies of essential machinery, inputs for the construction of needed plant and facilities, and technical skills, including organized services. Fourthly, this is an area in which there is already

an excellent example of co-opration between WHO, UNCTAD, UNIDO and the United Nations Action Programme for Economic Co-operation, particularly through the functioning of the joint task force on this subject. Finally, the adoption of the WHO "Global Strategy of Health for All by the Year 2000" lends urgency to the undertaking of this task.

154. The foregoing considerations suggest that the time is now ripe to distill the lessons of the experience of developing countries in working out new norms and standards for improving their access to the needed technologies in this sector. The stage is thus set for moving on to an international effort to evolve special norms and standards for the pharmaceutical sector. The problems connected with health in general, and the critical role of pharmaceuticals in particular, are such that attention could now be given to devising a code covering marketing, trade, distribution and transfer and development of technology in pharmaceuticals, paying special attention to the pressing needs of developing countries.

155. Several developments on the world scene have recently contributed to emphasizing that the task of establishing such a code is not only urgent but also highly feasible. A few of them may be recalled here for illustrative purposes.

(*a*) During the past few years the international community has gained considerable experience in establishing codes of conduct on problems affecting the vital interests of developed and developing countries: for example, by the adoption of the UNCTAD Code of Conduct for Liner Conferences and Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices, and the negotiation of an UNCTAD code of conduct on the transfer of technology and of a United Nations code of conduct on transnational corporations.

(*b*) Perhaps even more pertinent to the work on pharmaceuticals is the International Code of Marketing of Breast-milk Substitutes adopted by the Thirty-fourth World Health Assembly in May 1981.

(*c*) Several countries, developed as well as developing, have established national laws, regulations, directives, decrees or policy guidelines dealing with the pharmaceutical sector, including marketing, distribution, quality control, advertising and promotional activities concerning pharmaceuticals. Unfortunately, this experience has never been systematically analysed with a view to deriving standards and norms that could be reflected in an international instrument. But quite clearly a wide basis for the analysis of such experience exists in several countries.

(*d*) Perhaps of even more immediate relevance is the recent initiative of IFPMA, drawing upon the experience of certain of its members which have laid down their own codes of marketing practices. IFPMA has sought to generalize this experience by putting forward in March 1981 a "Code of Pharmaceutical Marketing Practices" that could serve as a model for its member associations.[68] It is explicitly stated in the preamble to the Code:

> It is believed that in keeping with the pharmaceutical industry's international responsibilities, the members of the Federation will be prepared to accept certain obligations, insofar as their marketing practices are concerned, and to ensure respect for them.

The Code consists of a preamble, followed by sections on the obligations of industry, general principles of marketing practices, medical representatives, symposia, congresses and other means of verbal communication, printed promotional material, and samples. There is thus already a basket of issues in terms of which IFPMA has organized the various obligations to be accepted and the principles, practices and standards to be followed.

(*e*) The representatives of non-governmental organizations from 27 countries, concluding a three-day conference in Geneva (27-29 May 1981), formed an international coalition called "Health Action International".[69] This body decided to address issues such as: an end to patent protection for essential drugs; progressive replacement of proprietary brands by generic drugs; decommercialization of essential drugs. It also referred to the need for a code on pharmaceuticals.

(*f*) The Tenth World Congress of the International Organization of Consumers Unions, held in June 1981 at The Hague, Netherlands, adopted a resolution which provided, in paragraph 5: "Congress requests IOCU, working through Health Action International to urge WHO and UNCTAD to adopt a code of practice for the marketing of pharmaceuticals."[70]

156. Codes have thus been formulated by several members of IFPMA, and the Federation itself has prepared a model code. The Governments of a number of countries have adopted certain regulatory and policy measures in this direction. The members of IOCU have urged that international bodies take up the task of establishing a code, and HAI has commented on the IFPMA Code.[71] Many currents have thus converged. The next practical step, therefore, may well be the convening of an expert group which, on the basis of preparatory work by the organizations, could review carefully the common elements in the endeavours mentioned above and begin the task of putting them together in a code that must necessarily reflect all relevant dimensions and all separate concerns, including in particular the special interests of the developing countries.

2. Progressive decommercialization of pharmaceutical technology

157. There are at present a large number of pharmaceutical technologies in the developed market-economy countries which are either publicly owned or freely available and which are often those required by most developing countries to meet the drug requirements of the population. However, because the availability of technologies in the public domain is often made subject to private decisions through a complex process of packaging and control of know-how, access by developing countries to such technologies is severely constrained. The supply of drugs under a large number

[68] See annex VIII below.

[69] See annex IX below.

[70] See annex X below.

[71] See annex XI below.

of brand names, particularly of drugs that are no longer subject to patent protection, imposes serious limitations on the ability of developing countries to initiate the production of essential drugs in quantities large enough to ensure efficient production.

158. In the socialist countries, all pharmaceutical technology is in the public domain or controlled by public enterprises. Even where these public enterprises may be regarded as private institutions from a legal point of view, the profit motive is not the main determinant of their actions or international transactions. In transactions entered into between enterprises in the socialist countries of Eastern Europe and those of developing countries, it has often been the practice to offer certain concessional terms with a view to promoting the development of the pharmaceutical industry in those countries. Such transactions are therefore not strictly speaking commercial transactions based upon market considerations.

159. There is a strong case for undertaking determined action to improve the access of developing countries to such pharmaceutical technologies on a progressively decommercialized basis. The Secretary-General of UNCTAD, in his statement to the United Nations Conference on Science and Technology for Development in Vienna on 22 August 1979, forcefully singled out pharmaceutical technology in this respect. He stated that "nowhere is the case for such progressive decommercialization of technology more urgent than in areas which cater to the satisfaction of critical basic needs—for example, pharmaceuticals, food and food processing, housing and building materials, public transport and energy supply".

160. The case for such progressive decommercialization of pharmaceutical technology has been made more urgent by the adoption at the Thirty-fourth World Health Assembly, in May 1981, of the "Global Strategy of Health for All by the Year 2000". Dr. H. Mahler, Director-General of WHO, evoking Jean-Jacques Rousseau, called the strategy a "social contract" for health—a contract in which the partners were the Governments and peoples of the world.[72] The executive summary of the Strategy emphasizes in paragraph 8 that "crucial to the Strategy is making sure of social control of the health infrastructure and technology through a high degree of community involvement".[73] That point was underlined by Mrs. Indira Gandhi, Prime Minister of India. She said: "My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death."[74]

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[72] WHO, *Verbatim Records of the Plenary Meetings of the Thirty-fourth World Health Assembly* (Geneva, 4-22 May 1981), p. 17, second plenary meeting.

[73] WHO, *Global Strategy for Health for All by the Year 2000* (*op. cit.*), p. 12.

[74] WHO, *Verbatim Records of the Plenary Meetings of the Thirty-fourth World Health Assembly* (*op. cit.*), p. 75, fourth plenary meeting.

161. The idea of the progressive decommercialization of pharmaceutical technology perhaps merits further clarification. It has two main elements. First, there is the importance of offering concessional terms for the transfer of pharmaceutical technology. In economic co-operation between developed and developing countries, the idea of such concessional terms, not guided by strict market considerations, has been very widely accepted. That idea has been put into practice in agreements on the international transfer of financial resources, food aid, terms offered by international or interregional lending institutions, and implementation of various projects, including those relating to infrastructure, manufacture, and health and similar areas. In all these cases, the guiding consideration has been that here are cases of urgent development needs that will remain unsatisfied if the flow of resources aimed at their satisfaction is guided solely by market forces. Similar resource and income transfers have been carried out by Governments within their territories to disadvantaged sections of the population. The vast increase in the provision of social services has in fact been made possible by giving importance to non-market, or non-commercial, considerations.

162. Secondly, such decommercialization of pharmaceutical technology does not have to be brought about all at once for all drugs. In view of the critical importance of meeting the pressing health needs of developing countries, a modest beginning could be made for the supply of essential drugs to all developing countries, and particularly to the least developed among them. It should be possible for the developed countries to make available without charge, or at a nominal charge, or at a charge significantly below prevalent commercial practice, certain pharmaceutical technologies required by developing countries which are in the public domain or are freely available. When the transfer of such technologies to developing countries is subject to private decisions, for example in respect of a packaging process or control of know-how, the developed countries could take measures to assist the transfer on concessional terms, especially of technologies required to meet critical health needs in developing countries.

163. Access by developing countries to critical pharmaceutical technology in the public domain is further constrained by lack of information on the nature of the technologies available and of the minimum degree of organization required to take advantage of them. The situation could be improved through the establishment in developed countries of the necessary institutions or mechanisms that would keep up-to-date registers of technologies in the public domain, to which developing countries could be given the freest and fullest possible access. Even if some costs were charged, they could be reduced to a minimum. Especially favourable conditions, particularly in terms of costs and availability of information, could be granted to the least developed countries.

B. Non-aligned Countries.
8. Fifth Summit, Colombo, 16-19 August, 1979
d. Resolution on Cooperation Among Developing Countries in the Production, Procurement and Distribution of Pharmaceuticals.

The Conference

Recalling the Non-aligned Action Programme for Economic Cooperation among developing countries adopted at the Conference of Foreign Ministers of Non-aligned Countries in Georgetown in August, 1972, and approved at the Fourth Summit held in Algiers in September, 1973,

Recalling also the Economic Declaration of that Summit calling for the further strengthening of economic cooperation among developing countries,

Noting the inclusion of the production and distribution of medicine and medical substances in the Lima Programme for Mutual Assistance and solidarity as an additional area of cooperation among developing countries,

Bearing in mind the possibilities for joint action by developing countries, identified in the study commissioned by UNCTAD on major issues in the transfer of technology to the developing countries in the pharmaceutical industry,

1. Endorses the recommendations of the Group of Experts on Pharmaceuticals which met in Georgetown in July 1976 and which proposes among other things:

(a) the preparation of a list of priority pharmaceutical needs of each developing country and the formulation of a basic model list of such needs as a general guideline for action by the developing countries;

(b) the establishment of a national buying agency to undertake the purchase and supply of pharmaceuticals;

(c) that in the context of the revision of the industrial property systems, consideration be given to excluding pharmaceutical products from the grant of patent rights or alternatively the curtailment of the duration of patents for pharmaceuticals;

(d) the elimination, wherever possible, of brand names and the adoption of the generic names for pharmaceuticals; and provision of information only from official sources;

(e) the establishment by each developing country of its own pharmaceutical industry as appropriate, beginning with formulation and packaging and building up to more complex production activities;

(f) the creation of Regional Cooperative Pharmaceutical Production and Technology Centres (COPPTECS), as proposed by UNCTAD and UNIDO, in order to draw up drug lists, to coordinate research and development, facilitate the transfer of technology, collect and disseminate information on pharmaceutical uses and prices and on the technological capabilities among member countries and also to coordinate the production and exchange of drugs between different member countries as well as between different regional centres;

2. Invites the relevant international organizations such as UNCTAD, UNIDO, WHO, and UNDP to assist in the achievement of the objectives outlined in operative paragraph 1 above with particular regard to the establishment of appropriate National Pharmaceutical Centres in developing countries and Regional Cooperative Pharmaceutical Production and Technology Centres (COPPTECS) among them;

3. Decides further that the Coordinator of the Trade, Transport and Industry Sector of the Non-Aligned Action Programme for Economic Cooperation among developing countries should take the necessary follow-up action to ensure early implementation of the provisions of this resolution.

ECDC Handbook : Documents of the Non-aligned countries and group of 77, 1983

B. Non-aligned Countries
10. Resolution No.8 on Economic Cooperation among Developing Countries in the Field of Pharmaceuticals.

The Sixth Conference of Heads of State or Government of Non-aligned Countries, meeting in Havana, Cuba, from 3 to 9 September, 1979,

Recalling the Non-aligned Action Programme for Economic Co-operation adopted at the Fifth Summit held in Colombo in August 1976.

Recalling also resolution 25 on Co-operation Among Developing Countries in the Producltion, Procurement and Distribution of Pharmaceuticals adopted at the same Summit,

Recognizing the importance of pharmaceuticals in promoting the health and well-being of the people of the developing countries,

Bearing in mind the need for increased co-operation among developing countries in ensuring the rationalization of production and distribution of pharmaceuticals in the context of the identification of the essential drug requirements of those countries,

1. Endorses the recommendations contained in the report entitled "Pharmaceuticals in the Developing World - Policies on Drugs, Trade and Production" presented by the Government of Guyana in its capacity as Co-ordinator of the Trade, Transport and Industry sector of the Non-Aligned Action Programme for Economic Co-operation, which propose among other things:

(a) The establishment during the next two years of at least three - but probably as many as six regional co-ordinating institutions (such as Regional Co-operative, Pharmaceutical Production and Technology Centres (COPPTECS) or Regional Pharmaceutical Centres), appropriately distributed in each developing region, to serve as the main links between national organizations in the region and to perform some of the following functions:

(i) Elaboration of drug lists and formulas;
(ii) pooled procurement, inventory control and forecasting systems at the regional level;
(iii) elaboration of legal principles relating to industrial property;
(iv) elaboration of tenders and master contracts for drug imports;
(v) provision of information on sources of supply and technology;
(vi) assisting in the screening and evaluation of drug imports;
(vii) price monitoring, control of transfer pricing and technology import mechanisms;
(viii) promoting industrial co-operation among member countries;
(ix) assisting in securing equipment imports on the most economic terms;
(x) organizing training of government officials in health policy, procurement, production, etc.;
(xi) the production of pharmaceuticals and intermediates for several countries;
(xii) research in laboratory, pilot plant, semi-industrial and industrial processes for the introduction of new products and the adaptation of imported technologies;
(xiii) the preparation of feasibility reports on pharmaceutical development projects;
(xiv) ensuring quality control in respect of raw materials, intermediates and finished goods.

....2/-

(b) The deployment of efforts to secure the establishment or expansion during the next two years of at least three formulation plants, but probably as many as six, appropriately distributed in each developing region;

(c) the production of medical plants for export or further processing and the establishment of national herbaria;

(d) production of apotherapeutics and active substances from gland and other abattoir by-products;

2. Expresses its appreciation to UNDP for financing the initial Project on Co-operation Among Developing Countries in the field of Pharmaceuticals and also to UNCTAD, UNIDO, WHO and the United Nations Department of Technical Cooperation for Development (UNDTCD) for the effective support provided to the Government of Guyana, in its capacity as Executing Agency, in the implementation of the Project;

3. Invites the Government of the developing countries and the relevant international organizations such as UNDP, UNCTAD, UNIDO and WHO to assist in the achievement of the objectives outlined in operative paragraph 1 above;

Decides that the Co-ordinator of the Trade, Transport and Industry sector of the Action Programme for Economic Co-operation should take the necessary action, in consultation with the Co-ordinator of the Health Sector of the Action Programme, to ensure the early implementation of the provisions of this resolution.

ECDC Handbook : Documents of the Non-aligned countries and group of 77, 1983

RESOLUTION ON COOPERATION AMONG DEVELOPING COUNTRIES IN THE PRODUCTION, PROCUREMENT AND DISTRIBUTION OF PHARMACEUTICALS

The Conference

Recalling the Non-Aligned Action Programme for Economic Cooperation among developing countries adopted at the Conference of Foreign Ministers of Non-Aligned Countries in Georgetown in August, 1972, and approved at the Fourth Summit held in September, 1973, in Algiers,

Recalling also the Economic Declaration of that Summit calling for the further strengthening of economic cooperation among developing countries,

Noting the inclusion of the production and distribution of medicine and medical substances, in the Lima Programme for Mutual Assistance and Solidarity as an additional area of cooperation among developing countries,

Bearing in mind the possibilities for joint action by developing countries, identified in the study commissioned by UNCTAD, on major issues in the transfer of technology, to the developing countries in the pharmaceutical industry,

1. *Endorses* the recommendations of the Group of Experts on Pharmaceuticals which met in July, 1976 in Georgetown, and which proposes among other things:

(a) the preparation of a list of priority pharmaceutical need of each developing country and the formulation of a basic model list of such needs as a general guideline for action by the developing countries;

(b) the establishment of a national buying agency to undertake the purchase and supply of pharmaceuticals;

(c) that in the context of the revision of the industrial property systems, consideration be given to excluding pharmaceutical products from the grant of patent rights or alternatively the curtailment of the duration of patents for pharmaceuticals;

(d) the elimination, wherever possible, of brand names and the adoption of the generic names for pharmaceuticals; and provision of information only from official sources;

(e) the establishment by each developing country of its own pharmaceutical industry as appropriate, beginning with formulation and packaging and building up to more complex production activities;

(f) the creation of Regional Cooperative Pharmaceutical Production and Technology Centre (COPPTECS), as proposed by UNCTAD and UNIDO, in order to draw up drug lists, to coordinate research and development, facilitate the transfer of technology, collect and disseminate information on pharmaceutical uses and prices and on the technological capabilities among member countries and also to coordinate the production and exchange of drugs between different member countries as well as between different regional centres;

2. *Invites* the relevant international organizations such as UNCTAD, UNIDO, WHO and UNDP to assist in the achievement of the objectives outlined in operative paragraph I above with particular regard to the establishment of appropriate National Pharmaceutical Centres in developing countries and Regional Cooperative Pharmaceutical Production and Technology Centres (COPPTECS) among them;

3. *Decides* further that the Coordinator of the Trade, Transport and Industry Sector of the Non-Aligned Action Programme for Economic Cooperation among developing countries should take the necessary follow-up action to ensure early implementation of the provisions of this resolution.

TWO DECADES OF NON-ALIGNMENT
DOCUMENT : 1983

The use of essential drugs

Second report of the WHO Expert Committee | Technical Report Series 722 | World Health Organization, Geneva 1985

2. GUIDELINES FOR ESTABLISHING A NATIONAL PROGRAMME FOR ESSENTIAL DRUGS

Since the first report on the selection of essential drugs was published in 1977, the concept of essential drugs has become widely recognized as useful. It has provided a rational basis not only for drug procurement at national level but also for establishing drug requirements at various levels within the health care system. In fact, many developing countries have already selected essential drugs according to their needs and the related programmes are, in some cases, in an advanced stage of implementation.

In order to ensure that an essential drugs programme is adequately instituted at national level, several steps are advised:

(1) The establishment of a list of essential drugs, based on the recommendations of a local committee, is the starting point of the programme. The committee should include individuals competent in the fields of medicine, pharmacology, and pharmacy, as well as peripheral health workers. Where individuals with adequate training are not available within the country, cooperation from WHO could be sought.

(2) The international nonproprietary (generic) names for drugs or pharmaceutical substances[1] should be used whenever available, and prescribers should be provided with a cross-index of nonproprietary and proprietary names.

(3) Concise, accurate, and comprehensive drug information should be prepared to accompany the list of essential drugs.

(4) Quality, including stability and bioavailability, should be assured through testing or regulation, as discussed in section 5. Where national resources are not available for this type of control, the suppliers should provide documentation of the product's compliance with the required specifications.

(5) Local health authorities should decide the level of expertise required to prescribe individual drugs or a group of drugs in a therapeutic category. Consideration should be given, in particular, to the competence of the personnel to make a correct diagnosis. In some instances, while individuals with advanced training are necessary to prescribe initial therapy, individuals with less training could be responsible for maintenance therapy.

(6) The success of the entire essential drugs programme is dependent upon the efficient administration of supply, storage, and distribution at every point from the manufacturer to the end user. Government intervention may be necessary to ensure the availability of some drugs in the formulations listed, and special arrangements may need to be instituted for the storage and distribution of drugs that have a short shelf-life or require refrigeration.

(7) Efficient management of stocks is necessary to eliminate waste and to ensure continuity of supplies. Procurement policy should be based upon detailed records of turnover. In some instances, drug utilization studies may contribute to a better understanding of true requirements.

(8) Research, both clinical and pharmaceutical, is sometimes required to settle the choice of a particular drug product under local conditions.

[1] See *International nonproprietary names (INN) for pharmaceutical substances: cumulative list no. 6*. Geneva, World Health Organization, 1982. Further lists of proposed and recommended INN are issued periodically as supplements to the *WHO Chronicle*.

3. CRITERIA FOR THE SELECTION OF ESSENTIAL DRUGS

Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms.

The choice of such drugs depends on many factors, such as the pattern of prevalent diseases; the treatment facilities; the training and experience of the available personnel; the financial resources; and genetic, demographic, and environmental factors.

Only those drugs should be selected for which sound and adequate data on efficacy and safety are available from adequate clinical studies and for which evidence of performance in general use in a variety of medical settings has been obtained.

Each selected drug must be available in a form in which adequate quality, including bioavailability, can be assured; its stability under the anticipated conditions of storage and use must be established.

Where two or more drugs appear to be approximately similar in the above respects, the choice between them should be made on the basis of a careful evaluation of their relative efficacy, safety, quality, price, and availability. In cost comparisons between drugs the cost of the total treatment, and not only the unit cost of the drug, must be considered. In some cases the choice may also be influenced by other factors, such as comparative pharmacokinetic properties, or by local considerations such as the availability of facilities for manufacture or storage.

In the great majority of cases essential drugs should be formulated as single compounds. Fixed-ratio combination products are acceptable only when the dosage of each ingredient meets the requirements of a defined population group and when the combination provides a proven advantage over single compounds administered separately in therapeutic effect, safety, or compliance.

THE MAIN RECOMMENDATIONS OF THE HATHI COMMITTEE WERE:

1. NATIONALIZATION OF MUTINATIONAL DRUG COMPANIES.
2. ESTABLISHMENT OF A NATIONAL DRUG AUTHORITY.
3. PRIORITY PRODUCTION OF 116 ESSENTIAL DRUGS.
4. ABOLITION OF BRAND NAMES AND INTRODUCTION OF GENERIC NAMES.
5. REVISION AND UPDATING OF THE INDIAN NATIONAL FORMULARY.
6. STRENGTHENING OF QUALITY CONTROL.
7. ELIMINATION OF IRRATIONAL DRUG COMBINATIONS.

The Committee on Drugs and Pharmaceuticals (commonly known as the Hathi Committee), appointed by the Ministry of Petroleum and Chemicals, Government of India, report submitted on April 1975.

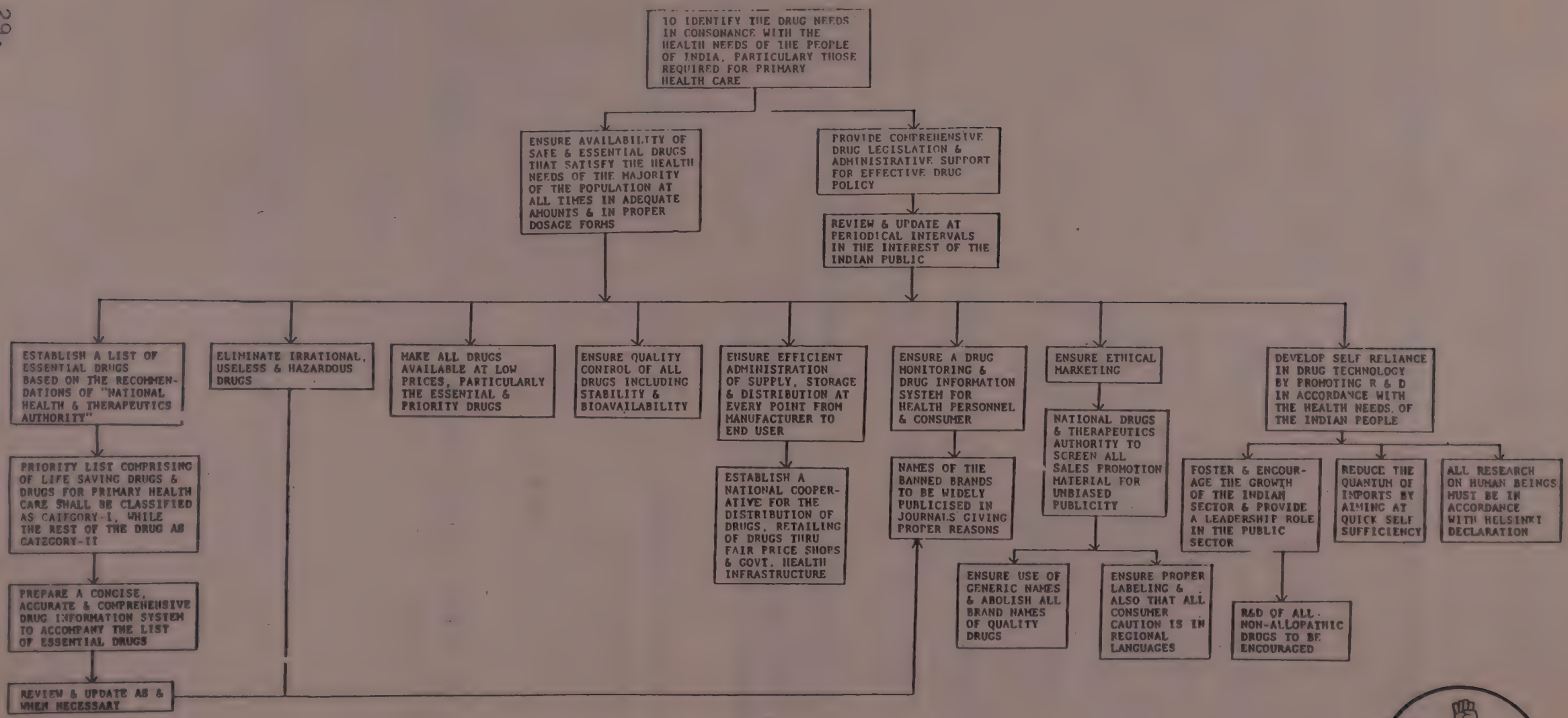
This Report provided the inspiration for the formulation of Bangladesh's National Drug Policy

YET

Not a single recommendation of the Hathi Committee has been implemented in India.

Annexure 2.7

AIMS & OBJECTIVES OF A RATIONAL DRUG POLICY



VHAI

The selection of essential drugs

World Health Organization
Technical Report Series 615

Report of a
WHO Expert Committee

World Health Organization Geneva 1977

3. GUIDELINES FOR ESTABLISHING A LIST OF ESSENTIAL DRUGS

Criteria for the selection of essential drugs are intended to ensure that the process of selection will be unbiased and based on the best available scientific information, yet allow for a degree of variation to take into account local needs and requirements. The following guidelines are recommended :

(1) Each country should appoint a committee to establish a list of essential drugs. The committee should include individuals competent in the fields of clinical medicine, pharmacology and pharmacy, as well as peripheral health workers. Where individuals with adequate training are not available within the country, assistance from WHO could be sought.

(2) Drug selection should be based on the results of benefit and safety evaluations obtained in controlled clinical trials and/or epidemiological studies. Guidelines for such trials have been set forth in the report of a WHO Scientific Group.[1]

(3) The international nonproprietary (generic) names for drugs or pharmaceutical substances should be used whenever available.[2] A cross-index of nonproprietary and proprietary names should initially be provided to the prescribers.

(4) Regulations and facilities should be available to ensure that the quality of selected pharmaceutical products meets adequate quality control standards, including stability and, when necessary, bioavailability. Where national resources are not available for this type of control, the suppliers should provide documentation of the product's compliance with the requested specifications.

(5) Cost represents a major selection criterion. In cost comparisons between drugs, the cost of the total treatment, and not only the unit cost, must be considered. In addition, the cost of nonpharmaceutical therapeutic modalities should be taken into account.

(6) Local health authorities should decide the level of expertise required to prescribe single drugs or a group of drugs in a therapeutic category. Consideration should also be given to the competence of the personnel to make a correct diagnosis. In some instances, while individuals with advanced training are necessary to prescribe initial therapy, individuals with less training could be responsible for maintenance therapy.

(7) The influence of local diseases or conditions on pharmacokinetic and pharmacodynamic parameters should be considered in making the selections : e.g., malnutrition, liver disease.

(8) When several drugs are available for the same indication, select the drug, pharmaceutical product and dosage form that provide the highest benefit/risk ratio.

(9) When two or more drugs are therapeutically equivalent, preference should be given to :

(i) the drug which has been most thoroughly investigated ;

(ii) the drug with the most favourable pharmacokinetic properties, e.g., to improve compliance, to minimize risk in various pathophysiological states ;

(iii) drugs for which local, reliable manufacturing facilities for pharmaceutical products exist ;

(iv) drugs, pharmaceutical products and dosage forms with favourable stability, or for which storage facilities exist.

(10) Fixed-ratio combinations are only acceptable if the following criteria are met :

(i) clinical documentation justifies the concomitant use of more than one drug ;

(ii) the therapeutic effect is greater than the sum of the effect of each ;

(iii) the cost of the combination product is less than the sum of the individual products ;

(iv) compliance is improved ;

(v) sufficient drug ratios are provided to allow dosage adjustments satisfactory for the majority of the population.

(11) The list should be reviewed at least once a year and whenever necessary. New drugs should be introduced only if they offer distinct advantages over drugs previously selected. If new information becomes available on drugs already in the list which clearly shows that they no longer have a favourable benefit/risk ratio, they should be deleted and replaced by a safer drug. It should be remembered that for the treatment of certain conditions, nonpharmacological forms of therapy, or no therapy at all, may be preferable.

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[1] WHO Technical Report Series, No. 563, 1975.

[2] See *International nonproprietary names (INN) for pharmaceutical substances: Cumulative list No. 3*, Geneva, World Health Organization, 1977. Further lists of proposed and recommended INN are issued periodically as supplements to the *WHO Chronicle* ; the latest lists of proposed INN (List 38) and of recommended INN (List 17) appeared as supplements to *WHO Chronicle*, 1977, Vol. 31, No. 9 and No. 10 respectively.

III

CONCEPT OF ESSENTIAL DRUGS

Confusion abounds in the minds of the consumers, health personnel and policy makers as regards **drug demands** and wants created by market forces as opposed to genuine drug needs.

The concept of essential drugs aims at providing much needed help in this selection process and in the way out of the 'pill jungle'. There is an urgent need for a clear understanding for what is meant by **rational, essential** and **priority drugs.**

The WHO Expert Committee on Essential Drugs attempted to provide guidelines to member countries to help them draw up a list of essential drugs:

> "It is clear that for the optimal use of limited financial resources the available drugs must be restricted to those proven to be therapeutically effective, to have acceptable safety and to satisfy the health needs of the population. The selected drugs are here called 'essential' drugs, indicating that they are of the utmost importance, and are basic, indispensable and necessary for the health needs of the population".
>
> "Drugs included in such a list would differ from country to country depending on many conditions, such as the pattern of prevalent diseases, the type of health personnel available, financial resources and genetic, demographic and environmental factors". (See Annexure 3.1).

It is evident, therefore, that the key elements in the concept of essential drugs are that, that they be

RATIONAL
- SCIENTIFICALLY PROVEN
- THERAPEUTICALLY EFFECTIVE
- ECONOMICAL and
- SOCIALLY ACCEPTABLE

Drugs have a definite role in health care. They are meant to help people and not to serve economic interest.

According to Health Action Internation (HAI) an international pressure group working towards rational drug policies and rational drug use, all drugs must:

1. **MEET REAL MEDICAL NEED**
   This means that their use is likely to improve the quality or extent of medical care.

2. **HAVE SIGNIFICANT THERAPEUTIC VALUE**
   This means that they must do what is claimed for them, and that patients will benefit from that.

3. **BE ACCEPTABLY SAFE**
   This means that their likely benefits must far outweigh risks.

4. **OFFER SATISFACTORY VALUE FOR MONEY**
   This favours the introduction and use of drugs which work as well as other medicines, but cost less.

AIDAN reiterates the above and it feels that the **Selection of Drugs** from amongst the different therapeutic categories should be based on

MEDICO SOCIAL JUSTIFICATION:
it should keep in mind -

- THERAPEUTIC EFFICACY
- SAFETY
- COST OF TOTAL COURSE OF DRUG TREATMENT NOT MERELY UNIT COST OF A DRUG
- EASE OF ADMINISTRATION
- LIMITED POTENTIAL FOR MISUSE
- INDIGENOUS PRODUCTION
- EASE OF TRANSPORT. STORAGE
- LONG SHELF LIFE

ESSENTIAL DRUGS RELATED DEFINITIONS

In drawing up the essential drug programme, it will be helpful to bear in mind the following concepts :

RATIONAL DRUGS — are those drugs which are accepted world-wide and included in the standard text books of medicine and pharmacology.

ESSENTIAL DRUGS — are those selected by each country according to health needs to its people. The 'Criteria of selection of essential drugs' suggested by WHO have been accepted by over 80 countries. In addition to these criteria, Norway has based the selection of essential drugs on **"efficacy", "safety"** and **"medical need".** This **medical need** clause precludes the registration of any new drug which is not "more effective" than one that is already in use, and which is not **safer** and **cheaper** than drugs currently used.

PRIORITY DRUG LIST — are drawn from among the essential drug list to give priority to drug **production, distribution** and **availability for use** in diseases having

- greater mortality (death)
- greater morbidity (illness)
- severe sequelae (after effects)
- communicability (T.B,Leprosy)

and for use in national programme such as T.B. and Malaria eradication, Blindness control, Goitre control, Immunization, etc.

GRADED ESSENTIAL DRUG LIST — drugs are needed for different levels of health personnel and health institutions. Bangladesh prepared such a graded list of essential drugs which indicated 12 drugs for use at village level; an additional 33 drugs for use at "thana" level; and 105 drugs for restricted and specialized use. (See Annexure 3.3).

NATIONAL DRUG FORMULARY

A National Drug Formulary is essential for the implementation of a rational drug policy. Such a Formulary should provide **therapeutic guidelines,** and **comparative costs.** The mere listing of essential drugs is inadequate and soon becomes meaningless. The Indian Drug Formulary which is a mere listing of drugs has not been updated since 1979.

A rational Formulary needs to be prepared along the lines of the British National Formulary, which should be updated annually.

ADVANTAGES OF THE CONCEPT OF ESSENTIAL DRUGS

Preparing a rational list of essential/restricted drugs has several advantages: medical, economic, social and administrative.

MEDICAL ADVANTAGES

§ It is **medically, therapeutically** and **scientificaiiy sound**, and it ensures rational use of drugs.

§ It **limits** the **use** of **irrationai** and **hazardous** drugs and **decreases** the risks of **iatrogenesis.**

§ It **improves** the possibility of **monitoring adverse drug reactions** in patients.

ECONOMIC ADVANTAGES

§ It is economically beneficial to the nation because it **prevents wastage of scarce resources** on **non-essentials.**

§ The **economies of scale** achieved in the larger production of priority drugs **brings down their prices.**

§ It **curtails** the **aggressive marketing** of **non-essential formulations.**

§ It is economically beneficial to the patient **because it prevents wastage on irrational and non-essentials.**

SOCIAL ADVANTAGES

§ It **responds** to the **real health needs** of the **people.**

§ It facilitates the **dissemination of correct information** about the drugs to health personnel, medical practitioners and consumers in general.

§ It **makes it imperative to draw up priorities** to meet the most urgent needs of the people for essential health care.

ADMINISTRATIVE ADVANTAGES

§ It is **organizationally sound** because it **makes quality control easier** because of the limited number of drugs to be monitored.

§ It **facilitates the streamlining** of **production, storage** and **distribution of drugs,** because of the smaller number of drugs involved.

§ It **helps** in the **clean identification of the drugs.**

§ It **facilitates** the **fixing of prices** as well as the **revision**/withdrawal of excise duties, sales tax etc.

*****

Annexure 3.1.

Table 1. Analgesics

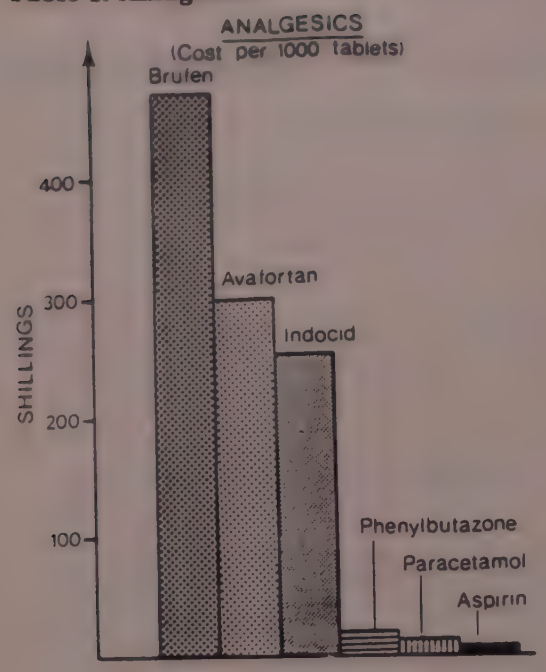


Table 2. Anti-hypertensives

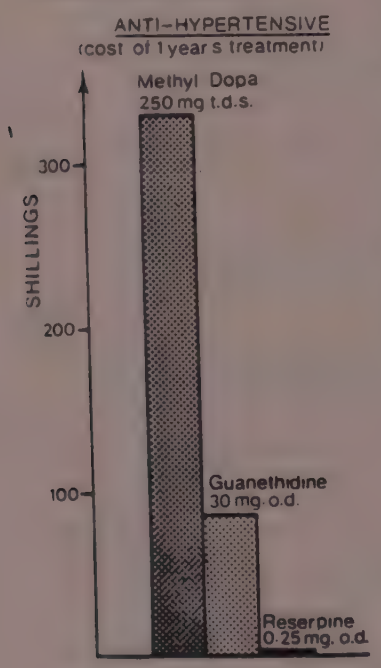


Table 3. Tranquillizers

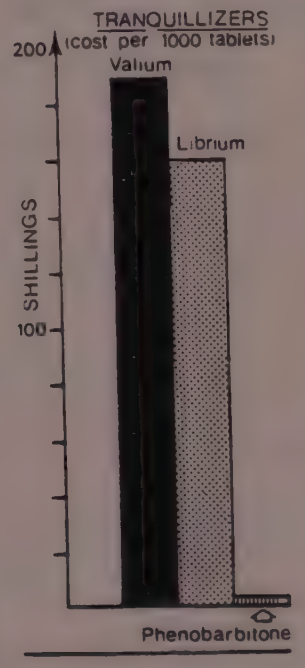
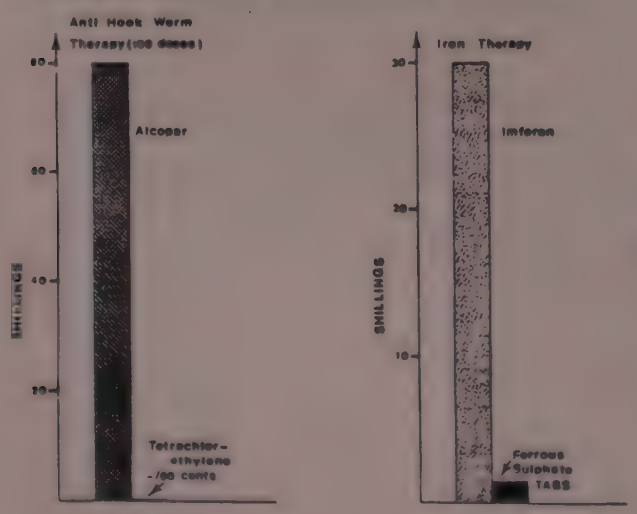


Table 4. Treatment of Hookworm Anaemia



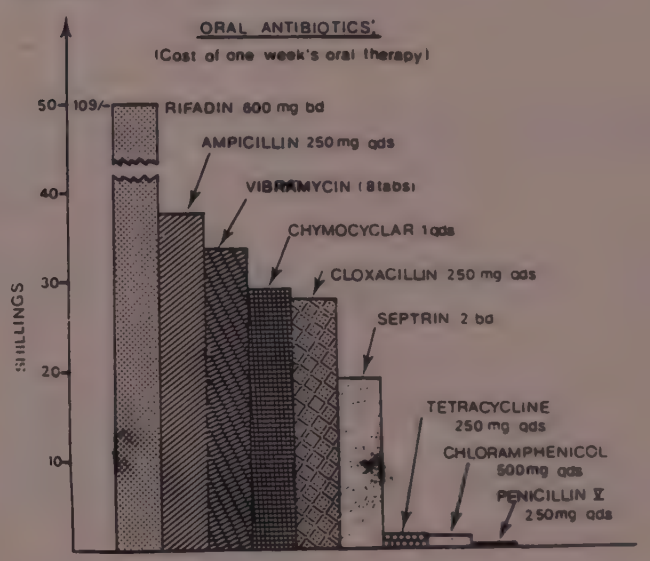
Tropical Doctor, April 1975

Pharmacological Notes

Cost-effectiveness and drug therapy

A. N. P. Speight, MRCP

Table 5. Cost of one week's oral antibiotic therapy



Penicillin V at 50 cents, chloramphenicol at 1/70, and tetracycline at 1/95 per week are all 10–50 times

Table 6. Cost of one week's parenteral antibiotic therapy

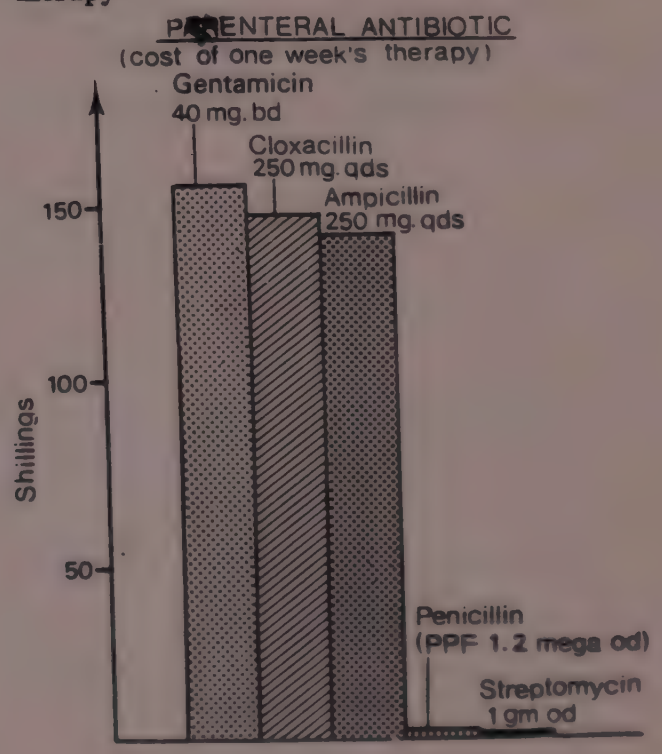


Figure II.A.4.

Therapeutic Categories for a National Drug List

1. Anaesthetics
2. Analgesics, Antipyretics, Nonsteroidal Antiinflammatory Drugs and Drugs Used to Treat Gout
3. Analgesics, Narcotics, and Narcotic Antagonists
4. Antiallergics (Antihistamines)
5. Antidotes
6. Antiepileptics
7. Antiinfective Drugs
   - 7.1. Amoebicides
   - 7.2. Antihelminthic drugs
   - 7.3. Antibacterial drugs
   - 7.4. Antifilarial drugs
   - 7.5. Antileprosy drugs
   - 7.6. Antimalarials
   - 7.7. Antischistosomals
   - 7.8. Antitrypanosomals
   - 7.9. Antituberculosis drugs
   - 7.10. Leishmaniacides
   - 7.11. Systemic antifungal drugs
8. Antimigraine drugs
9. Antineoplastic and Immunosuppressive Drugs
10. Antiparkinsonism Drugs
11. Blood, Drugs Affecting the
    - 11.1. Antianaemia drugs
    - 11.2. Anticoagulants and antagonists
12. Blood Products and Blood Substitutes
13. Cardiovascular Drugs
    - 13.1. Antianginal drugs
    - 13.2. Antiarrhythmic drugs
    - 13.3. Antihypertensive drugs
    - 13.4. Cardiac glycosides
    - 13.5. Drugs used to treat shock or anaphylaxis
14. Dermatological Drugs
15. Diagnostic Agents
16. Diuretics
17. Gastrointestinal Drugs
    - 17.1. Antacids
    - 17.2. Antiemetics
    - 17.3. Antihemorrhoidals
    - 17.4. Antispasmodics
    - 17.5. Cathartics
    - 17.6. Diarrhea
      - 17.6.1. Antidiarrheal
      - 17.6.2. Replacement solution
18. Hormones
    - 18.1. Adrenal hormones and synthetic substitutes
    - 18.2. Androgens
    - 18.3. Estrogens
    - 18.4. Insulins
    - 18.5. Oral contraceptives
    - 18.6. Progesterones
    - 18.7. Thyroid hormones and antagonists
    - 18.8. Ovulation inducers
19. Immunologicals
    - 19.1. Sera and immunoglobulins
    - 19.2. Vaccines
20. Muscle Relaxants (peripherally acting and Cholinesterase Inhibitors)
21. Ophthalmological Preparations
22. Oxytocics
23. Peritoneal Dialysis Solution
24. Psychotherapeutic Drugs
25. Respiratory Tract, Drugs Acting on the
    - 25.1. Antiasthmatic drugs
    - 25.2. Antitussives
26. Solutions Correcting Water, Electrolyte, and Acid-Base Disturbances
    - 26.1. Oral
    - 26.2. Parenteral
27. Surgical Disinfectants
28. Vitamins and Minerals

Abstracted from WHO Technical Report Series, No. 641, "The Selection of Essential Drugs", 1979.

Source :
Management Sciences for Health
Boston, USA.

Managing Drug Supply
The Selection, Procurement, Distribution and use of Pharmaceuticals in Primary Health Care

Appendix II.A.2.

Example of a Drug List Structured by Therapeutic Category and Level-of-Use

THERAPEUTIC CATEGORY	LEVEL-OF-USE			
Name of Drug	Community Health Workers	Dispen-saries	Health Centers	Hospitals
A. ANESTHETICS				
Anesthetic ether			x	x
Halothane			x	x
Sodium pentothal			x	x
Lidocaine		x	x	x
B. ANALGESICS				
Aspirin	x	x	x	x
Codeine			x	x
C. GASTROINTESTINAL PREPARATIONS				
Hyoscyamine sulfate		x	x	x
Magnesium trisilicate		x	x	x
Mineral oil			x	x
D. ANTI-ALLERGICS				
Diphenhydramine		x	x	x
E. SEDATIVES				
Diazepam (injectable)			x	x
Phenobarbital		x	x	x
F. ANTI-PARASITICS				
Metronidazole			x	x
Mebendazole			x	x
Piperazine	x	x	x	x
G. ANTI-TUBERCULARS				
Isoniazid			x	x
H. ANTI-MALARIALS				
Chloroquine phosphate (capsules)	x	x	x	x
Chloroquine phosphate (injectable)			x	x
I. ANTIBIOTICS				
Penicillin (tablets and suspension)		x	x	x
Penicillin (procaine and benzathine)			x	x
Triple sulfa tablets		x	x	x
Chloramphenicol (tablets and suspension)			x	x
Tetracycline syrup			x	x

Source:

Management Sciences for Health
Boston, USA.

Managing Drug Supply
The Selection, procurement, distribution and use of pharmaceuticals in Primary Health Care.

J. VITAMINS AND MINERALS				
Multivitamins with folate and iron (capsules and liquid)	x	x	x	x
Ferrous sulfate (capsules and liquid)	x	x	x	x
Vitamin A	x	x	x	x
Vitamin K			x	x
K. RESPIRATORY SYSTEM MEDICATIONS				
Phenylephrine		x	x	x
Epinephrine			x	x
Aminophylline		x	x	x
L. OPHTHALMIC PREPARATIONS				
Silver nitrate		x	x	x
Sulfacetamide solution	x	x	x	x
Tetracycline ointment		x	x	x
M. DERMATOLOGICAL PREPARATIONS				
Gentian violet	x	x	x	x
Benzyl benzoate		x	x	x
Calamine lotion	x	x	x	x
N. CARDIAC AND ANTI-HYPERTENSIVE MEDICATIONS				
Epinephrine			x	x
Digitoxin			x	x
Reserpine		x	x	x
Chlorthiazide			x	x
O. HORMONES				
Insulin (regular)			x	x
Cortisone (injectable)			x	x
P OXYTOCICS				
Ergometrine maleate			x	x
Q. BLOOD SUBSTITUTES				
Dextran			x	x
R. ELECTROLYTE SOLUTIONS				
Oral rehydration packets	x	x	x	x
5 % Dextrose			x	x
Lactated ringers			x	x
Normal saline			x	x
S. VACCINES AND IMMUNOLOGICALS				
Antitetanus serum			x	x
DPT		x	x	x
Tetanus		x	x	x
Polio		x	x	x
Rubeola		x	x	x
T. CONTRACEPTIVES.				
Oral contraceptive tablets		x	x	x

Source:
Management Sciences for Health
Boston, USA

Managing Drug Supply
The Selection, procurement, distribution and use of pharmaceuticals in Primary Health Care.

IV

IMPLEMENTATION OF ESSENTIAL DRUG CONCEPT

Selection of a theoretical essential or priority drug list if it is in the absence of ensuring adequate production, distribution or availability of the drug is useless.

An essential drug list consisting of 116 drugs was drawn up by the Hathi Committee in 1975. The act of selection was not followed up by the act of implementation. Even Drugs required for national Priority programmes have not had a better fate.

It is ironical that while the list of 200 essential drugs of WHO was considered too painfully short by the drug industry, and officials from the associated ministries - the decrease in number of essential drugs to 95 was considered adequate by the NDPDC. This decrease in the number of essential drugs to 95 was recommended by the National Drugs & Pharmaceutical Development Council. It was aimed at minimising the size of "drug price control market" and had more to do with drug pricing than essentiality of the drugs.

This has obviously distorted the entire concept of selection of priority drugs which should be based on efficacy, safety and cost.

The drugs in WHO list which have been excluded from NDPDC's priority list are nevertheless still essential - treating them at par with other non-essntial drugs is not appropriate. Making recommendations, suggestions and blue prints for promotion of drug production for national programmes without creating the mechanisms to ensure production is futile, as is evident from cases of severe shortages of Vitamin A for Blindness control program, iodized salt for Goitre control and anti TB drugs for TB Control Program.

SETTING DEMAND TARGETS

The criteria used by the NDPDC demands is based mainly on inaccurate drug production figures and past distorted growth trends rather than on present assessment of health problems and drug needs. See the following:

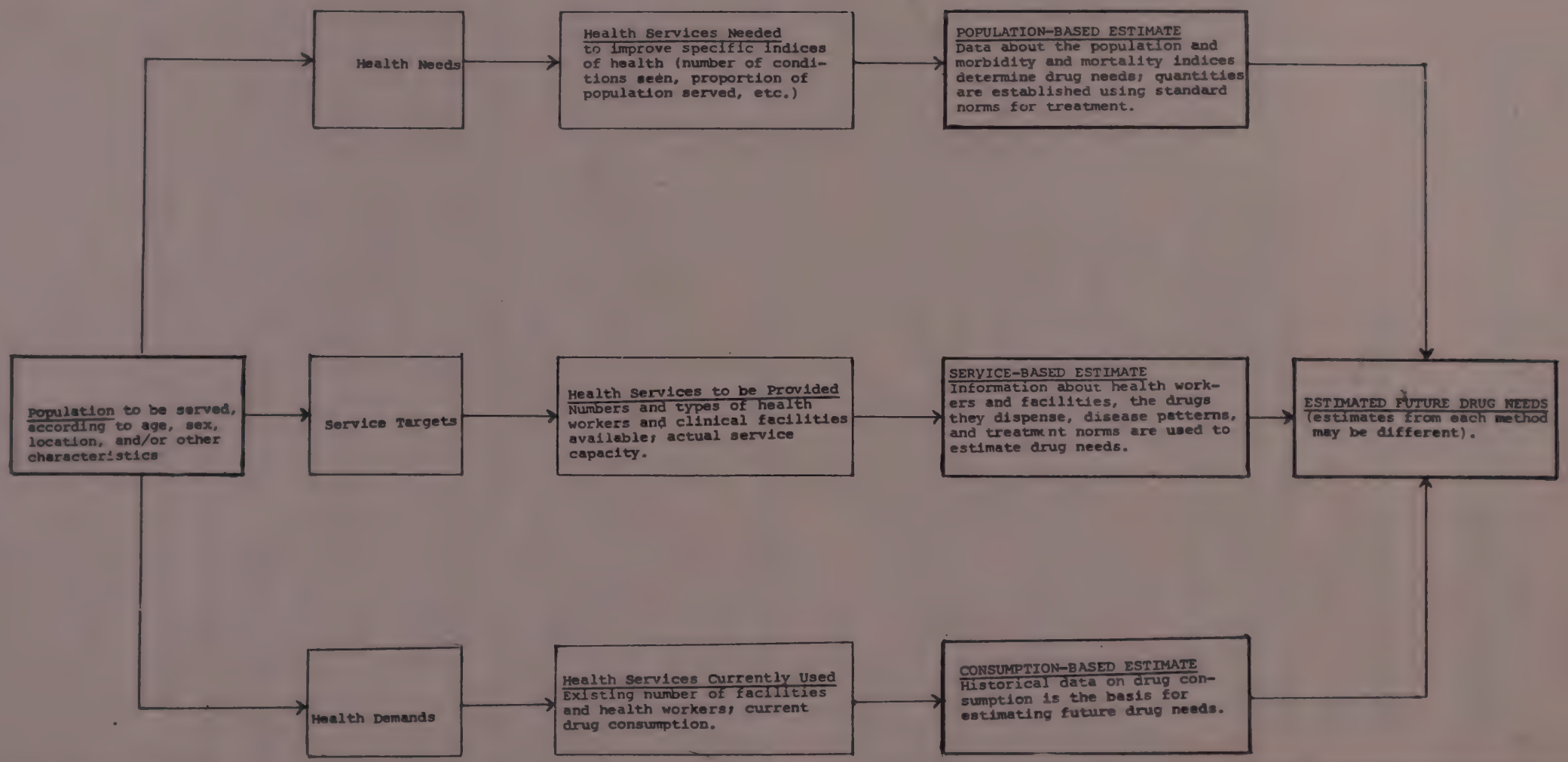
"It may be observed that under present conditions because of lack of essential data it is not possible to predict the requirement of individual drugs with sufficient accuracy. The Committee relied on the following essential criteria for assessment of demand:

i) Past Trend of production of the drug.
ii) Past Trend of import of drug.
iii) Past actual annual growth rate and its total availability (production + import, less export) in comparision with those anticipated by the sixth plan working group of Drug and Pharmaceuticals.
iv) Trends in growth rate of various formulations as per ORG report.
v) Obsolescence of the drug and anticipated introduction of new drugs with less side reactions and better substitutes being available.
vi) Requirement of the drugs in National Health Program.
vii) Anticipated Export of bulk drugs and formulations
(Report of the Working Group on Planning and Development NDPDC Feb. 1984).

Except for VI all the other criteria are based on past production patterns and not on current needs.

. 6 out of the 7 criteria are linked with past growth trends.
. The Drug Policy has based its drug production targets more on market demands than on health needs.
. Categorisation of a drug as an Essential life saving drug and recognition of it being needed for a national control program means nothin in terms of drug production and availability in the present situation.
. Asking for 20% Essential drug production without creating the machinery for ensuring its production will mean nothing. The estimates of drug requirements must keep in mind the health needs; service targets and health demands (Please see chart :).
. Three methods of Estimating Drug Requirements.

Three Methods of Estimating Drug Requirements



ESSENTIAL DRUGS

DELHI, HINDUSTAN TIMES, 10.9.85

Govt. urged to raise Vitamin A output

NEW DELHI, Sept. 9 (UNI)—The All-India Drug Action Network (AIDAN), a premier voluntary agency, has urged the Government to take immediate steps to increase domestic production of Vitamin A.

The production of Vitamin A, lack of which renders about 30,000 children blind every year, has fallen drastically, AIDAN coordinator Miss

THE ECONOMIC TIMES, 2.12.85

Shortage of two vital antibiotics

From Our Own Correspondent

BOMBAY, December 1.

The sources say that although about 150 tonnes of penicillin G is produced in the country by two public sector units — Hindustan Antibiotics and Indian Drugs and Pharmaceuticals — most of it is being used for formulations

DELHI, Patriot 23.6.85

Anti-TB drug shortage

by Rahil Rajkumar

The Bombay bulk-drugs dealers and manufacturers are complaining of an acute shortage of rifampicin, an anti-TB drug.

THE ECONOMIC TIMES. 1.1.86

DRUG PRODUCTION

DECLINE IN PENICILLIN, VIT. A PRODUCTION

For instance, Vitamin A is a controlled item and it is marketed as vitamin A palmitate (oily) and vitamin A acetate (dry powder). Roche and Glaxo are the major producers of vitamin A. During 1984-85, there was a decline in the output of Vit A. In the case of Roche, production after having risen from 38.23 MMU in 1982-83 to 40.73 MMU in 1983-84 declined to 37.60 MMU in 1984-85. In Glaxo also output after rising from 44.25 MMU in 1982-83 to 19.51 MMU in 1983-84, fell to 16.56 MMU in 1984-85. However, the quantity of Vit A imported also after rising from 12.425 MMU in 1982-83 to 20.346 MMU in 1983-84, dropped to 12.685 MMU in 1984-85.

Production of some drugs like penicillin, strepto-sulphate, amoxycillin, paracetamol, phenobarbitone, sulphadimidine, sulphamethoxadole, sodium PAS, trimethoprim, vitamin B-2 and maicin showed declines for IDPL during 1984-85. On the other hand, output of tetracycline, oxytetracycline, 6-APA analgin, methyl dopa, sulphaquanidine and niacinamide showed increases in 1984-85. Admittedly, IDPL has achieved breakthrough in the technology of a limited number of drugs, enabling it to increase the output and capacity utilisation.

NEW DELHI.
THE ECONOMIC TIMES, 6 July '85.

Drug shortage

Dilantin in an essential medicine for treatment of grand mal (epilepsy). According to specialists, it is to be taken thrice a day without fail to be effective. Failure to conform to the prescription may prove harmful to patients. Such a vital medicine is not available in CGHS dispensaries in the market. The director-general of health service must take speedy action to meet the situation.

RAJNI MATHUR

850 Sector 12
R. K. Puram
NEW DELHI-22

DELHI Patriot 18.7.85

Life-saving drug in short supply

Our Staff Reporter

DELHI

The shortage of a life-saving drug Persentune is causing concern to the heart-patients in the Capital.

MADRAS THE HINDU 18.10.84

Drug shortage and the cure

THE SHORTAGE OF essential drugs is no new phenomenon in the country. What is disconcerting is that the efforts to set right the position and avoid such recurrence have been weak. According to medical opinion any discontinuance of the use of, say Pilocarpin for instance, produces an irreparable loss of vision. It is therefore, of the utmost importance that a steady flow of such drugs is maintained. Only a few months back the Union Minister for Chemicals and Fertilizers admitted in Parliament that shortages of at least five drugs were reported.

MADRAS THE HINDU. 29 May, '85

Life-saving drugs vanish from market

MADRAS, May 28.

Quite a few life-saving drugs have disappeared from the market in Madras. Tablets like Emdopa (an anti-hypertensive drug), Persantin, Lanoxin and Dytide (prescribed for cardiac patients) and Incidal (given to those suffering from allergy) are not available for the past two months.

Incorrect categorisation of drugs had led to the shortage of life-saving drugs. The Government had asked the manufacturers not to charge a profit margin of over 40 per cent, which includes overheads, for drugs under Category I, and 55 per cent for drugs under Category II. For Categories III and IV, the manufacturers are given a free hand to fix the prices

life-saving drugs compulsorily, if they wanted to make other drugs. If the Government wanted to reduce prices, it should abolish all taxes and duties on life-saving drugs.

Mr. Vinod Khanna, Executive Committee member of the Tamil Nadu Chemists and Druggists Association, says retailers could not be blamed as they get the standard

DISTORTED PLANNING PRIORITIES

A very strong indication of the need for a more rational and coherent planning for the production of essential drugs is the fact that, from a study of the table 5.1, it is clearly evident that no provision is being made to increase the production of some essential drugs like INH needed for the national T.B. Control programme; while, on the other hand, the planning provides for a significant increase in the production of controversial drugs like hydroxyquinoline and oxyphen butazone.

The mid-term appraisal of the Working Group to project demand estimates of bulk drugs for the years 1984-85 to 1989-90 indicated no increase whatsoever in the demand for INH during the Seventh Plan period from 1985 to 1990. The projected demand remains constant at 250 tonnes for each year between 1985 to 1990 (see table 5.1)

If one bears in mind that in the past the actual production of essential drugs fell short of the estimated targets even though industry had the required capacity to meet the targets, it becomes evident that the reason for the shortfall in production is related to the profitability of the drug in question and NOT to the needs of the national health programmes such as the T.B. eradication programme. In contrast the planned increase of drugs like Hydroxyquinoline & Oxyphenbutazone is ironical.in the same table 5.1

This highlights, once again, that the planning of production targets for basic drugs is influenced not by the health needs of the country, but by the need to ensure the profitability of production for the drug industry.

This basic and serious flaw in the planning process needs to be corrected urgently.

MID-TERM APPRAISAL OF WORKING GROUP DEMAND ESTIMATES OF BULKDRUGS

FOR THE YEAR 1983-84 TO 1989-90

Table 5.1

Sl. No.	Name of the Bulk Drugs	A/C Unit	Total 79-80	Availability 80-81	81-82	During 82-83	Projected Growth Rate during 82-83 84-85%	Revised Estimates 83-84	Demand 6th plan 84-85	Projected growth Rate during 7th Plan %	7th Plan demand 85-86	86-87	87-88	Estimates 88-89	89-90
	ANTIBIOTICS														
1.	PENICILLIN For Formulations	MMU	340	350	360	370	5	390	410	5	430	450	480	500	520
	for Drug intermediates														
2.	STREPTOMYCIN BASE	T	290	270	290	250	20	620	740	20	890	1070	1285	1540	1950
	ANTI-TB DRUGS														
1.	PAS AND ITS SALTS	T	490	420	270	290	-	270	270	-	270	270	270	270	270
2.	INH	T	140	190	150	200	NIL	250	250	NIL	250	250	250	250	250
3.	THIACETAZONE	T	13	34	45	49	20	240	290	20	350	415	500	600	720
4.	ETHAMBUTOL	T	120	65	105	120	5	53	55	5	60	60	65	65	70
5.	PYRAZINAMIDE	kg	5540	15430	20160	16570	20	150	180	20	215	260	310	370	450
6.	RIFAMPICIN	kg	5410	8950	1670	24830	25	43750	54690	25	68350	85450	107810	133510	166890
	ANTI FILARIALS														
1.	DEC CITRATE	T	22	28	33	44	10	22000	24000	10	26400	29040	31940	35140	38650
	ANTI LEPROTICS														
1.	DDS (DAPSONE)	T	26	25	44	66	10	50	55	10	61	67	73	81	89

(continued...)

Sl. No.	Name of the Bulk Drugs	A/C Unit	Total 79-80	Availability 80-81	81-82	During 82-83	Projected Growth Rate during 82-83 84-85%	Revised Estimates 83-84	Demand 6th plan 84-85	Projected growth Rate during 7th Plan %	7th Plan demand 85-86	86-87	87-88	Estimates 88-89	89-90
ANTI MALARIALS															
1.	CHLOROQUINE	T	90	110	225	295	15	81	93	15	107	123	141	162	186
2.	AMODIAQUIN	T	38	23	26	30	10	370	400	10	440	485	530	590	645
3.	QUININE AND SALTS	MT	16	16	15	N.A.	15	35	40	15	46	53	61	70	80
4.	PRIMAQUIN	kg	60	70	140	100	-	20	-	20	20	20	20	20	20
TI-DYSENTRY DRUGS															
	METRONIDAZOLE	T	90	120	130	160	5	105	110	5	116	122	228	134	141
A.	IODOCHLOROHYDROXY QUINOLINE	T					20	190	230	20	280	330	400	480	572
B	DI-IODOHYDROXY	T						260	280	10	310	340	380	416	460
C.	INTESTOPAN SUBSTANCE	T						90	100	10	110	120	130	145	160
D	HALOGENATED OXYOUINOLINE	T	230	230	265			50	55	10	60	70	70	80	90
D.	HALOGENATED OXYQUINOLINE	T	230	230	265	365	10	400	440	10	480	530	580	640	705
	TINIDAZOLE	T	NA	0.29	21	32	15	37	42	15	48	56	64	73	84
	DILOXANIDE FUROATE	T	13	17	18	27	10	30	33	10	36	40	44	48	53
	FURAZOLIDINE	T	39	64	115	NA	10	125	140	10	155	170	185	205	225
ANALGESICS/ANTIPYRETICS ETC.															
.	ANALGIN	T	450	970	1190	920	NIL	1000	1000	NIL	1000	1000	1000	1000	1000
.	ASPRIN	T	1290	1070	1250	1400	10	1550	1700	10	1870	2060	2200	2490	2740
.	PHENYLBUTAZONE	T	55	75	110	100	NIL	100	100	NIL	100	100	100	100	100
.	OXYPHENIBUTAZONE	T	50	60	70	80	15	95	110	15	125	145	165	190	220
.	PARACETAMOL	T	110	590	810	1230	15	2880	3300	15	3800	4370	5030	5780	6650

SOURCE : NDPDC Steering Committee Report, 1984.

V

Example of Distorted Planning Priorities

A. The Case of T.B.

T.B. is known as the white plague - public health enemy No. 1 and undoubtedly a disease of poverty.

10 million Indians are estimated to be affected by T.B.
2.5 million of these are infectious
5,00,000 die each year from T.B.

§ Studies carried out in Chingleput Dist. of Tamil Nadu show that BCG vaccines have been found to be ineffective in preventing pulmonary T.B.

§ A single patient with T.B. infects 8 to 12 persons within a period of 2 years if he is untreated or wrongly treated.

§ The treatment for T.B. is of a long duration : minimum of 1 year, but averaging 18 months.

§ Costly anti-T.B. drugs, Rifampicin & Ethambutol are not available free to the patients under the National TB control program.

Early diagnosis and treatment of T.B. is critical if the affected person has to be helped.

On the national level, adequate production, easy availability and affordable price of anti-T.B. drugs is essential for rational T.B. Care,

Y E T

According to the ICMR-ICSSR report "Health For All-an alternative strategy" (1981), India produces only one-third of the requirement of anti T.B. drugs.

Table 5.2 provides a projected demand for bulk drugs for treatment of T.B. for the years 1979-80 to 1984-85. A close study of the comparative figures shows that although demand for INH for the year 1980-81 was projected at 240 metric tonnes, this target was scaled down to 154 m.t., and the actual production in that period was only 129.2 m.t.

Similarly, for the years 1981-82 and 1982-83, the study reveals that against a projected demand of 290 and 300 m.t. respectively, the targets were scaled down to 140 and 158 m.t. Unfortunately, even these reduced targets were not met. The actual production of INH was 110.4 and 128 m.t. in 1981-82 and 1982-83.

What is the reason ?

Is it that the Indian drug industry is not capable of producing anti-T.B. drugs of the required capacity?

Table 5.2 shows that the industry has a much higher installed capacity. This capacity is under-utilized.

Not only is the production of anti-T.B. drugs far short of the targets, but drugs like Streptomycin, which are needed for treatment of T.B., are marketed in irrational, and even hazardous combinations. While there is an acute shortage of streptomycin (it is not available at District T.B. Centres and PHCs), one finds plenty of Inj. Streptomycin in combination with penicillin.

These injections are used widely for fevers, infections, etc. This is irrational because it can mask T.B., and can lead to the development of resistance to streptomycin by T.B. Bacilli (mycobacterium tuberculosis).

TABLE 5.2

Production and Target of Monitored Bulk Drugs
Production Programme of Monitored Bulk Drugs.

Drug	Unit	1980-81		1981-82		1982-83		1983-84	1984-85
		Target	Prodn.	Target	Prodn.	Target	Prodn.		
STM	MT	302.0	227.33	320.00	225.46	320.00	239.60	238.31	235.06
INH	MT	154.0	129.20	140.00	110.40	158.00	125.43	105.72	127.70
Thiacetazone	MT	20.0	8.44	16.4	13.98	21.0	25.09	12.40	20.39
Ethambutol	MT	33.0	23.87	32.00	66.92	154.00	97.23	147.79	205.50

Source : Indian Drugs Statistics
1982-83, 1984-85.

(DEMAND PROJECTION FOR BULK DRUGS)
Country's Requirement of T.B. Drugs

S.No.	Name of the Drug	Unit	1979-80	80-81	81-82	82-83	83-84	84-85	Growth %
1.	Streptomycin	MT	300	330	363	400	440	485	10%
2.	Rifampicin	Kg	5,400	7,300	9,800	13,300	18,000	24,000	35%
3.	I N H	MT	200	240	290	350	415	500	20%
4.	P A S	MT	600	630	660	700	730	770	5%
5.	Thiacetazone	MT	40	42	44	46	48	50	5%
6.	Ethambutol	MT	60	78	101	132	170	225	30%
7.	Pyrazinamide	Kg	8,000	8,400	8,820	9,260	9,725	10,200	5%

Source : Indian Drugs Statistics
1982-83

(...Table 5.2 contd)

T.B. TABLE-III

Table 5ANTI TB drug Production Pfizer

	Actual production in metric tons			
	1980	1981	1982	1983
Licensed Drug Capacity PAS 110	23.8	13.78	5.7	NIL.
INH 80	73.77	54.00	71.57	NIL.

Source: Amitava Guha Zonal Sec. FMRAI
in "Glimpse of the Drug industry in India"

Again, one can find plenty of streptomycin in combination with chloramphenicol. This combination is widely (mis) used in the treatment of diarrhoea. This use of combination-streptomycin and chloramphenicol is not only a waste (because 60% of diarrhoeas are viral and can be controlled with ORT & they do not need anti-bacterials), but is highly hazardous because it unnecessarily exposes people to the risks of chloramphenicol - a drug that should be reserved for typhoid fevers. Used in combination, it leads to the development of resistance of typhoid to chloramphenicol. Over 10,000 Mexicans died in 1975 due to Typhoid resistance to Chloramphenicol. Such resistance is now being reported increasingly in India.

Example of distorted planning priorities

B. The case of Vitamin A

Nutritional deficiency of Vitamin A leads to blindness.

§ Vit. A deficiency is a leading cause of blindness in pre-school children.

§ Vit. A deficiency leads to higher infant mortality. (See Table 5.3).

§ It is associated with diarrhoeal diseases and measles both of which are rampant in India.

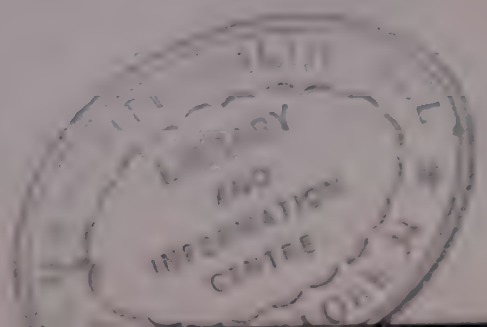
§ In India, 40,000 children become blind each year for want of adequate intake of Vit. A.

§ 42% of India's population is below the age of 15 years. With the increase in the child population, the requirement of Vit A should be increasing proportionately.

§ The increasing non-availability of foods rich in Vit. A for the poor majority makes the production of Vit A more urgent to prevent the increase in nutritional blindness.

§ Ensuring a good nutritional base which provides adequate Vit. 'A' is the only sensible long term solution.

ORT = Oral Rehydration Therapy



Y E T

The production of Vit. A has not only shown any increase IT HAS ACTUALLY DECREASED (see Table 5.3 & 5.4)

§ The production of Vit. A in 1984 was 17.88 tonnes less than in 1980 (37.57% less)

§ It was 53.08 tonnes (50.55%) less than the target for 1984.

§ The import of Vit. A in 1984 was 7.661 tonnes less than in 1983.

While Vit. A for children is becoming increasingly unavailable, it is being used in veterinary and poultry feed and to enrich edible oils. Recognising these additional requirements production of Vit. 'A' should show a significant increase.

Why does our policy not provide for increase in the production of Vitamin A, which is so essential for the well-being of our children?

Why is it that while there is a decrease in the production of Vit. A, there is a corresponding increase in the production of tonics of doubtful value and cough syrups?

To further complicate the situation, industry is promoting second-line drugs without ensuring their rational use. This, of course is understandable because of the higher mark-ups allowed for Category III drugs, which makes it more profitable for the drug industry. However, not only are these second-line drugs more expensive for the patients, but their un-monitored

use can result in the emergence of resistance. If this happens, it will be truly disastrous. The efficacy of these drugs is at no point doubted but their availability to the poor is.

One has to understand this problem in the light of the fact that the overall number of T.B. patients is increasing.

It is claimed that the incidence of T.B. has not shown any increase. But this is statistical jugglery. The total increase in the population of those affected by T.B. is increasing significantly with the increase in the population.

TABLE 5.3

VITAMIN 'A' PRODUCTION

DISPARITY BETWEEN NEED AND PRODUCTION

On comparing production and targets of monitored bulk[1,2] Drugs.

	Unit	1980-81		1981-82		1982-83		1983-84		1984-85	
		T	P	T	P	T	P	T	P	T	P
Vit'A'	MMU	66.0	59.8	66.6	52.6	77.0	52.0	90.0	60.23	105	41.92

Target increased by 57.5% and Production decreased by 30%

(T=Target, P=Production)

1. Narayana, P.L.;"The Indian Pharmaceutical Industry Problems & Prospects". Table No.7, page no.244 - National Council of Advanced Economic Research, 1981.
2. Up-dated Ministry of Chemicals, Fertilizers Annual Report 1984-85, page 38.

DETERIORATING VIT.'A' PRODUCTION TRENDS

Vit.'A' Deficiency

As a response to Sri Jaganath Patnaik's unstarred Loksabha question 6371, Mr. Veerendra Patil said that Vit.'A' is a canalised item and main item marketed as Vit.'A' Palmitate (oily) and Vit.'A' Acetate (dry powder).

M/s Roche and Glaxo are the major producers of Vit.'A' and the entire production of Vit.'A' in the country during 1982-83 and 1983-84 was from these two companies.

Their production in MMU :

	1982-83	1983-84	1984-85
Roche	38.24	40.72	37.60
Glaxo	14.25	19.51	16.56

DEPENDENCE ON IMPORTS - WASTAGE OF FOREIGN EXCHANGE.

	1982-83	1983-84	1984-85
Total quantity of Vit.'A' imported (in MMU)	12.425	20.346	12.685

TABLE 5.4

S.No.	Name of the Co.	Name of Formulation	Composition	Pack Size	Nos. of the units produced during the year ended December -		
					1982	1983	1984
1.	M/s Roche Products	Arovit Tabs	Vit'A' 50,000 10 per tab.	8's	22,37,336	21,77,927	21,25,428
2.	-do-	Arovit Drops	1,50,000 10 per amp.	7.5 amp	,20,233	11,195	6,686
3.	-do-	Arovit Inj.	1 lakh 10 per amp.	3 amp	2,67,250	2,35,308	1,79,199
4.	-do-	Arovit Forte	3 lakh 10 per amp.	3 amp	1,93,164	1,46,686	1,42,119
5.	-do-	Rovigon Tab	Each tab. contains: Vit'A'10,000 10 Vit'A' 25 inj	8's	17,68,533	14,52,019	13,34,547
6.	M/s Glaxo Lab.	Prepaline Caps.	24,000 IV	100's	64,148	42,525	42,965
7.	-do-	Prepaline Inj.		1 ml.	23,790	19,364	4,014
8.	-do-	Prepaline Inj. (Forte)		1 ml.	4,34,651	3,80, 806	28,956

Reply of Minister, Chemicals & Fertilizers, Mr. Veerandra Patil on 14th May in Lok Sabha, Unstarred Question 6371.

I THE STATE OF THE WORLD'S CHILDREN 1986

UNICEF

THE VITAMIN A STORY

Chart A Mortality rates in relation to eyesight status, (indicator of vitamin A status)

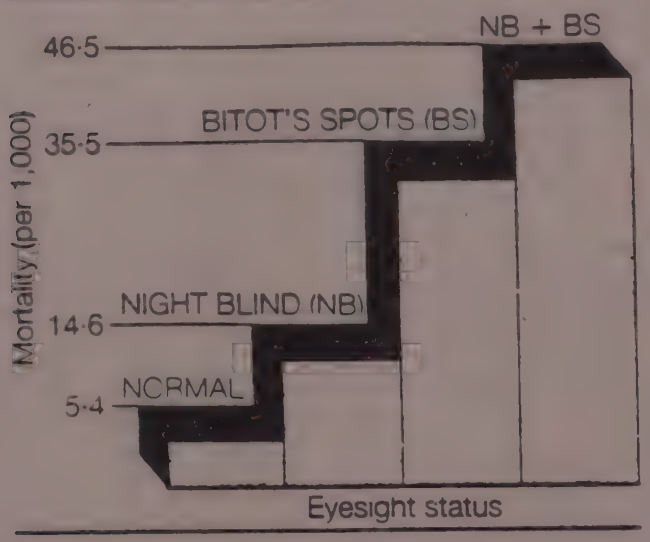
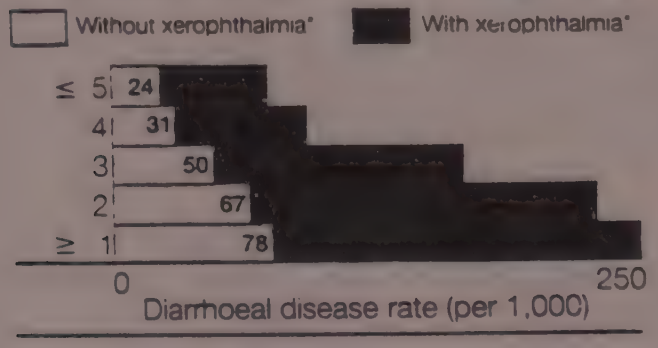
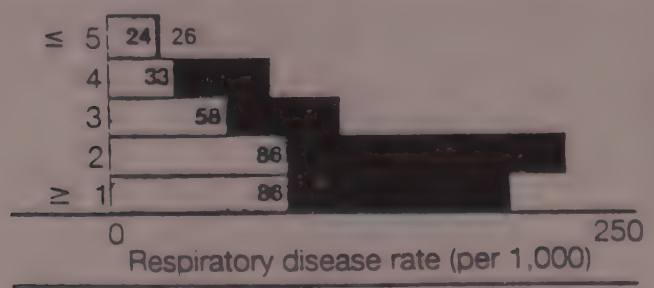


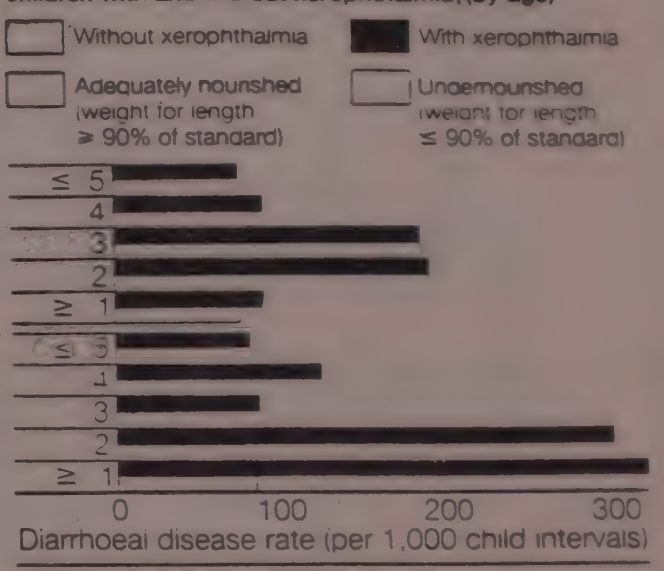
Chart B Incidence of diarrhoeal and respiratory disease among children with and without xerophthalmia, (by age)





*Without xerophthalmia = Children with normal eyes at both the start and end of the 3 month observational interval. With xerophthalmia = Children with mild xerophthalmia (night blindness and/or Bitot's spots) at both the start and end of the interval.

Chart C Incidence of diarrhoeal and respiratory disease among adequately nourished and undernourished children with and without xerophthalmia, (by age)



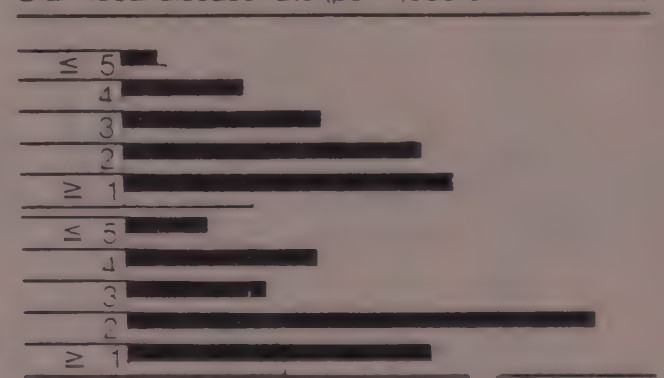
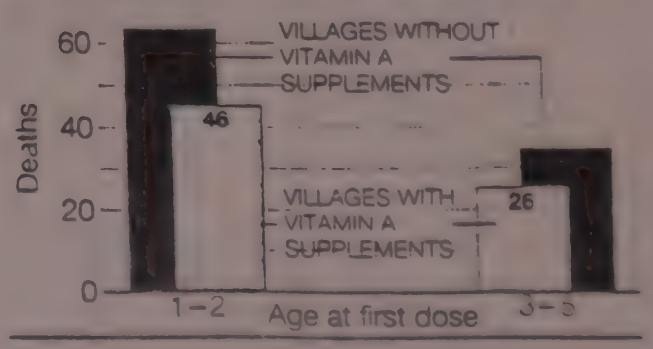


Chart D Age-specific mortality, (preliminary results)



The above graphs show the relationship of Vit.'A' deficiency with significantly higher infant mortality. Vit.'A' deficiency means life-long disability due to blindness and also increased chances of death.

VI

HAZARDOUS AND IRRATIONAL DRUGS

There are about 8,000 pharmaceutical units in India, which are producing approximately 60,000 drug formulations. many of these formulations are known to be irrational and even hazardous.

MOST DRUG COMBINATIONS ARE IRRATIONAL

* they increase cost unnecessarily
* they increase chances of drug interaction
* they make quality control difficult
* they make drug pricing and price control difficult
* they make monitoring of adverse drug reactions difficult
* they confuse consumers and medical practitioners alike.

The WHO List of Essential Drugs which consists of 250 drugs contains only seven combinations.(Technical Report Series 722, 1985)

In 1980, the Drug Consultative Committee, a statutory body constituted under Section 7 of the Drugs and Cosmetics Act (Act 23 of 1940), nominated a sub-committee of experts to study the rationality of 34 categories of fixed dose combination drugs. This sub-committee was to recommend to the DCC whether these combination drugs should be allowed or withdrawn.

The sub-committee formulated norms to allow combinations of drugs. These were :

a) if there is synergistic action
b) where there is corrective action
c) when two or more drugs are normally prescribed together and taken by the patient simultaneously
d) when the dosage of each of the drugs need not be individualized.
e) where a fixed-dose combination would ensure better patient compliance due to convenience of administration

f) where two or more drugs, prescribed separately may lead to non-ingestion of one of the drugs, thus adversely affecting the health of the patient

Conversely, norms for NOT allowing fixed dose combinations were formulated as follows :

a) where adverse interactions may occur
b) when one of the combined drugs becomes toxic or prolonged use
c) when abruspt withdrawal of one of the drugs may cause withdrawal symptoms
d) if sub-therapeutic doses are used in the absence of clinically demonstrable synergism
e) when pharmacokinetic behaviour of the individual agents is grossly different.

34 categories of combination drugs were evaluated and on the basis of these criteria, the sub-committee recommended a ban on 23 combination drugs and gave reasons for recommending the ban. Sixtten categories of these drugs were recommended to be weeded out immediately, while 7 of the categories were recommended to be weeded out over a specified period.

The list of 23 combinations to be weeded out is given on pg.

The sub-committee submitted its report to the Drug Consultative Committee on the 10 October 1981. It was also presented to the Drug Technical Advisory Board, and to the Ministry of Health and Family Welfare, which accepted these recommendations in 1981. The Drug Technical Advisory Board (a statutory body constituted under Section5 of the Drugs and Cosmetics Act of 1940) recommended banning of eighteen fixed dose combination drugs. It decided to prohibit the manufacture of fixed dose combinations of bronchodilators, antihistaminics and tranquilizers with corticosteroids as early as October 1980.

By some incomprehensible logic, the Drug Technical Advisory board, consisting of exactly the same members reversed its decision on December 31, 1981 and allowed the sale of the products which it had earlier considered

to be dangerous. At this point of time, it claimed that it was necessary to obtain wider medical opinion.

The Editor of MIMS in his editorial in the issue of February 1982 (Vol. 2 No.3) on the "somersault on steroids" said that "they must have had very extraordinary reason to

- reverse their own earlier decision
- ignore the advice of the Drug Consultative Committee
- consider the opinion of the whole battery of eminent and distinguished medical specialists from research institutions as inadequate so as to ask for further details and wider medical opinion."

The consumer who is exposed to these hazardous drugs is entitled to know the reason/s for the volte-face. This has, however, not been forthcoming.

RECOMMENDATIONS FOR WITHDRAWAL OF HAZARDOUS, IRRATIONAL AND THERAPEUTICALLY USELESS DRUGS

* All existing drugs available in the Indian market should be screened by an appropriate, impartial authority, such as the National Drug Authority recommended by the Hathi Committee.
* Those drugs which have life-threatening or serious side-effects, and for which safe alternatives are available should be banned with immediate effect.
* No fixed dose combinations should be allowed if an alternative single ingredient drug is available, except in accordance with the norms laid down by WHO.
* Information regarding the action taken by other countries to ban hazardous and irrational drugs, and their reasons for doing so (together with supporting medical/research evidence) should be made available to the public.

* The criteria for the withdrawal of hazardous and/or irrational drugs which have an unacceptably high risk factor, which are prepared in sub-therapeutic doses, or which are marketed in irrational combinations, should be widely publicized for the benefit of medical practitioners and the general public. The criteria used by the Scandinavian countries,Sri Lanka,Bangladesh,Mozambique etc. can be used as guidelines (see Appendix)

* Once a decision is made that a particular drug or drug combination is hazardous or irrational or useless, immediate steps must be taken to destroy all existing stocks and to stop further production immediately.

* Legislation should be suitably modified to ensure that Courts do not grant stay orders against decisions to destroy existing stocks of hazardous drugs, or to stop further production of such drugs forthwith. This is necessary in the interest of public health.

* After screening by the proposed National Drug Authority, only those drugs which are approved, should be re-registered with the Government. All other products should be withdrawn from the market, and further production banned. In line with the practice followed by other countries, it should be made mandatory for all drugs to be re-registered periodically e.g. every five years.

EXAMPLE OF HAZARDOUS DRUG

The Case of Clioquinols. **A**

Fact Sheet about Clioquinols

(Mexaform like Drugs.) - These drugs were widely used for the treatment of diarrhoes, and were even prescribed as prophylactics. Because of their known hazards and their doubted efficacy most countries with effective health and drug regulatory authorities have decided to withdraw them.

This is its story in brief -

1934 Drug introduced for diarrhoes and amoebic dysentry.

1935 First cases of toxic side effects reported by doctors from Argentina.

1939 Internal Documents of Ciba-Geigy (later released in Japanese courts) showed that "experiments of the drugs with cats and dogs had proven fatal".

Early '60s Swiss and Swedish Veterinarians reported that dogs treated with Enteroviofoform died with epileptiform seizures.
Warning circulated by company Headquarters among veterinarians not to use these drugs for veterinary treatment.
However the drugs were continued to be produced for human use No warning given infact its - SAFETY CONTINUED TO BE STRESSED.

CLIOQUINOL TOXICITY STARTED BEING REPORTED FROM EARLY 1960's :

Classical picture of SMON i.e. Sub Acute Myelo Optic Neuropathy is as follows :

- Ascending numbness in both legs
- severe pain in both the legs
- Loss of bladder control
- blindness

1965 - 450 cases of SMON reported in Japan
- Dr. Olle Hansson, Sweden, reported first case of Blindness in Lancet.

1969 - 2,340 cases reported in Japan

1970 - Over 11,000 cases of SMON diagnosed in Japan (according to some estimates, upto 30,000 people were affected).

Women and elderly found particularly vulnerable.

1973 - Journal of American Medical Association, 23rd July 1973 reported that neurological symptoms with Clioquinol were reported by clinicians from England, Australia, Switzerland.

1976 Dr. Olle Hansson, Paediatric Neurologist from Sweden proposed a boycott of all Ciba-Geigy products for continued sales of the drug inspite of its known hazard and doubtful efficacy.

1977 - Company continued to deny that
* SMON had anything to do with the drug.
* it sponsored study to prove the 'viral' and 'genetic theory as cause of SMON.

1978 According to WHO Information Jan-March '78 PDT/DI/78.1 efficacy of hydroxyquinolines for amoebiosis was questioned:

"Hydroxyquinolines are active only on organisms (i.e. amoebae present within the intestine...) used alone, therefore, they are active only in the absence of significant tissue invasion - a development that cannot be excluded with certainty even in patients with asymptomatic amoebiasis."

April 1979 Kyoto International Conference on "Drug Induced Suffering" held in Japan to focus on the fact that SMON was not limited to Japan and was a drug induced suffering.

1979 ICMR Committee
reviewed the situation and recommended a prospective study at several neurological centres.

1981 Ciba-Geigy lost 25% of their market in Sweden because of the boycott by over 3000 doctors for the continued sales of hydroxyquinolines in third world countries by their company.

1982 38 individuals in Sweden affected by side-effects of Mexaform sued Ciba-Geigy for damages. 1.8 million Swedish Kroners paid to Swedish SMON victims in an out-of-court settlement.

The Tokyo District Court gave its judgement after 8 years and 4 months from the time the first SMON damage suit was brought against the STATE and 3 pharmaceutical companies Ciba-Geigy, Tanabe and Takeda.

The court verdict was that:

(1) Clioquinol caused SMON

(2) Ciba-Geigy et al were liable because of their FAILING TO PASS ON INFORMATION

to the doctors & consumers
about the hazards (even though these hazards were known to the Company).

Apology of Ciba Geigy is attached as Annexure - 6.1.

1982 Ban of hydroxyquinoline combinations ordered by Drug Controller of India to be effective from 1.11.82. This was extended to 31.3.83 through D.O. No. X19013/8/81D dated 13.8.1982.

1984 Ciba-Geigy announced its decision to withdraw its products Mexaform and Enterovioform worldwide by end of March 1985.

1986 Clioquinol is banned in several developed countries and also in several developing countries such as Pakistan, Nepal, Sri Lanka, Bangladesh and Malaysia.

This hazardous drug :

- which is considered unsafe even for animals;
- whose continued sales led over 3,000 Swedish doctors to boycott all Ciba-Geigy products;
- which led to the withdrawal from the market by Ciba-Geigy of two of its best selling products: Mexaform and Enterovioform ;
- and for which the Japanese SMON victims set aside part of their compensation to create public awareness about the dangerous side-effects resulting from its use;

WAS RECENTLY GIVEN A CLEAN CHIT BY THE HEALTH MINISTRY IN THE INDIAN PARLIAMENT !! !!

(see figure 6.2)

Annexure 6.1

APOLOGY TO SMON PLAINTIFFS BY CIBA-GEIGY (Japan), LTD.

The following written apology was submitted to the plaintiffs by Ciba-Geigy (Japan), Ltd. through the Tokyo District Court on December 9, 1976, prior to settlement in the SMON litigation. (Translated from Japanese)

On June 10 in this court we, Ciba-Geigy (Japan), Ltd., asked the judges to guide us to a settlement; we have subsequently made similar requests in many other courts throughout Japan. During this period, we have heard the opinions of the plaintiffs regarding our proposal, and at the same time, when plaintiffs have been examined individually in this and other courts, we have heard the grievances of the plaintiffs and their families.

These grievances were all earnest expressions of their pain, distress, and anger; appeals were made for redress. They were heartrending cries that made us realize anew that SMON has caused the patients and their families unimaginable misery.

Since the beginning of this lawsuit, the plaintiffs and their representatives have told the court of many sufferings caused by the SMON disease. It has been repeatedly stressed that only a SMON patient can truly understand his fellow patients' sufferings. We believe that we must solemnly accept these grievances. We who manufactured and sold clioquinol drugs deeply sympathize with the plaintiffs and their families in their continuing unbearable agony; there are no words to adequately express our sorrow. In view of the fact that medical products namufactured and sold by us have been responsible for the occurrence of this tragedy in Japan, we extend our apologies, frankly and without reservation, to the plaintiffs and their families.

We realize, as the plaintiffs and their representatives have stressed that the sufferings of the SMON patients and their families can never be atoned for by material consolation alone. We fully understand that health, once lost, can never be restored again; our only possible course is to seek, with the guidance of the court, conciliation in good faith with the SMON plaintiffs.

We have also realized, with regret, that when we recently asked the court to act as mediator we neglected to adequately express our sincerity.

Again, we deeply apologize to the plaintiffs and their families.

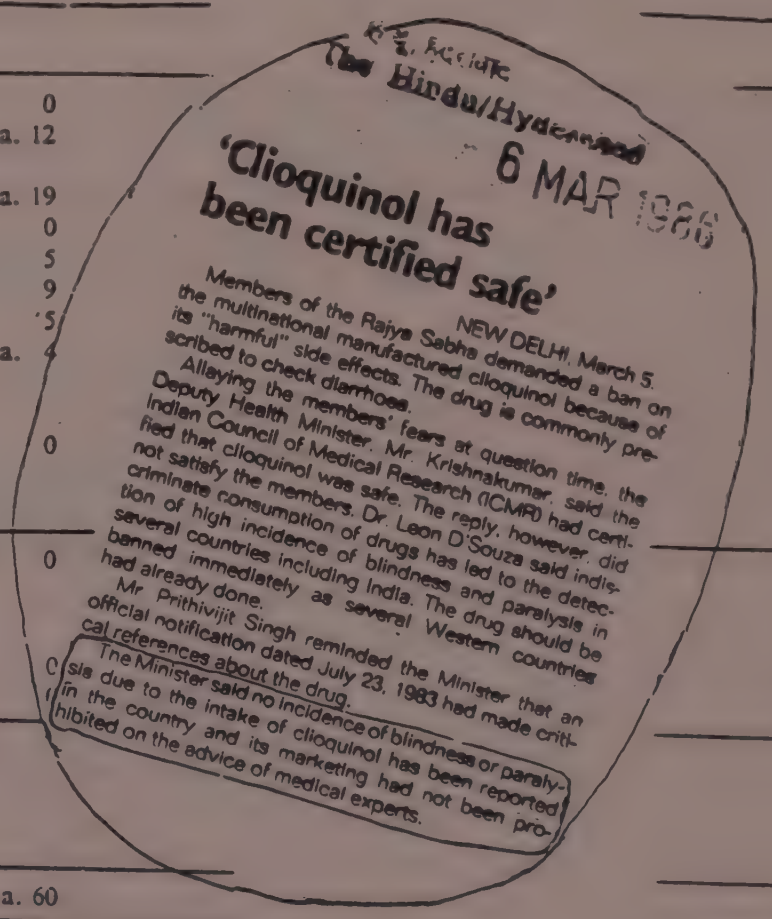
source : Geneva Press Conference on SMON
Proceedings
April 28, 1980, Geneva

Annexure 6.2

An international survey on the recent reports concerning intoxication with halogenated oxyquinoline derivatives and the regulations against their use*

TABLE 1. *Number of reported cases of intoxication with HOQ outside Japan*

Country •	Number of cases published after 1970	Number of cases reported in the mail survey	Number of reported cases (Ciba-Geigy Ltd.) 1962-71[1]	1935-75[2]
U.S.A.	5* (1)[3]	4		27
Canada	1	2		1
India	9	0****	6	11
Indonesia	3 (3)			1
Singapore	1 (1)			1
U.K.	9 (6)	0	8	9
France	10 (3)	ca. 12	1	10
Switzerland	6 (1)		13	16
F.R. Germany	5 (3)	ca. 19	22	30
Austria	2**	0		3
Sweden	14	5	3	6
Denmark	4	9		4
Norway	0	5		3
Netherlands	7	ca. 4	9	8
Belgium	2		2	2
Poland	1			1
Spain	1	0		1
Italy	1			1
Finland			1	3
Israel	2 (2)	0		1
Lebanon	1			2
Iran	1			
Australia	9***			
New Zealand	0	0	12	30
Curacao				2
Colombia				1
Brazil				1
Argentina				2
Total	94 (17)	ca. 60		3
			77	179



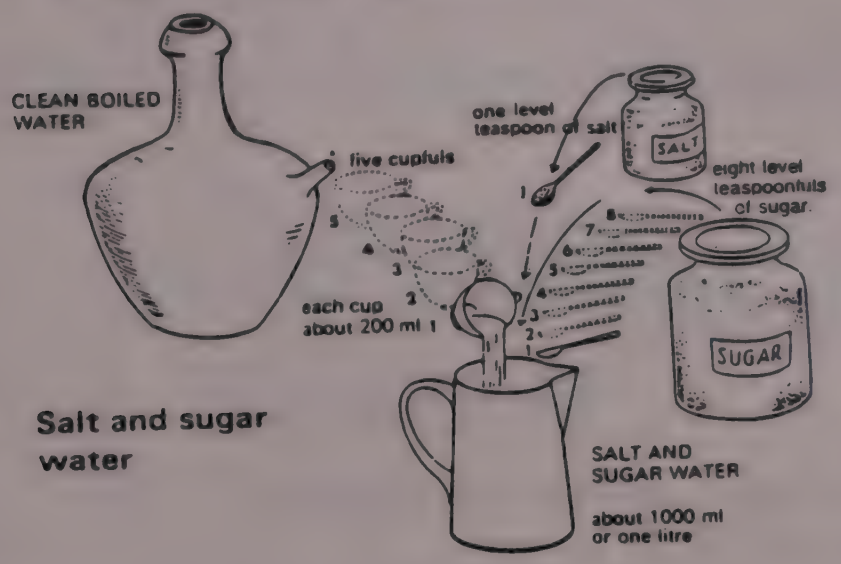
[1]Documentary evidence of S.M.O.N. Lawsuit Kanazawa District Court. Hei-187.
[2]Documentary evidence of S.M.O.N. Lawsuit Kanazawa District Court. Hei-321.
[3]Numbers in parentheses are suspected cases, cases which are difficult to be determined as HOQ intoxication for lack of sufficient description or because the articles have not been obtained yet.
*Besides, Prof. Tsubaki reported a 51-year-old woman. (Tsubaki, T. Personal communication)
**Besides, Prof. Wewalka reported a 36-year-old man. (Igata, A. Personal communication)
***29 cases including these were reported at Honolulu Symposium in Jan. 1976.
****'No reports of controlled study' was the reply.

Source: "Drug Induced Sufferings", Medical, Pharmacological & Legal Aspects Ed.1980, p.442.

*This work was supported by a special grant from the Ministry of Health and Welfare of Japan.
**Iodochlorhydroxyquinoline, broxyquinoline, halquinol, dioxidehydroxyquinoline, chlorquinaldol.

PREPARATION OF ORT SOLUTION

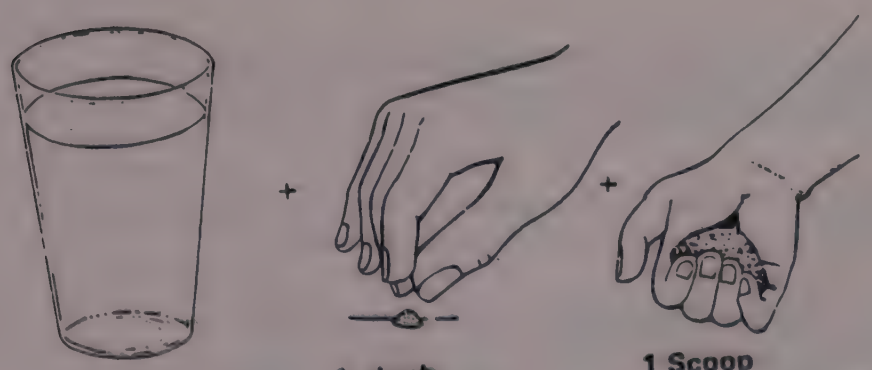
A simple salt and sugar solution can be made at home as follows:



Salt and sugar water

Source : " PRIMARY HEALTH CARE "
A manual for health workers
– Maurice King

It is usually preferable to make smaller quantities at a time:



1 glass
(200 c.c.)
water

1 pinch
(three fingers)
salt

1 Scoop
(four fingers)
sugar

Source: "A Taste of Tears"
Health Action Series 1
V H A I

ORT - (Oral Rehydration Therapy) Annex. 6.4

Potentially the most important medical breakthrough of this century.

- Lancet, Vol.II, p.300
5 Aug. 1978.

- In all cases of severe prolonged diarrhea, no matter what the cause, the rapid and complete correction of water and electrolytes loss is of the utmost importance.

  - Bevan, J.A. (ed.
  Essentials of Pharmacology,
  Harper & Row 1976, p.301.

- ORT has halved diarrhoea deaths in Guatemala, Egypt, Honduras.

- In Costa Rica with ORT deaths from dehydration decreased by more than 80% in hospitals.

- Trinidad child deaths from diarrhoeal disease dropped by 60% in 5 years in General Hospital Port of Spain with ORT replacing I/V infusion as main treatment for diarrhea.

- Haiti at the State University Hospital Port-au-Prince diarrheal death rate after introduction of ORT in 1980 decreased from 40% to 1 %.

- Jordan - 1720 out of 1732 cases of diarrhea were successful treated by ORT in General Hospital at Omman.

- 3 year study in Bangladesh of over 30,000 cases of diarrheal infections showed 95% could be successfully treated with ORT.

- Even in U.K. it was found that simple rehydration therapy was the most effective diarrhea treatment.

  - Breadshaw, C. "Treating children with diarrhea & Vomiting",
  The Practioner, vol.228,
  sept. 1984, p.834-835.

B

EXAMPLE OF HAZARDOUS DRUG COMBINATION

CHLORAMPHENICOL & STREPTOMYCIN COMBINATIONS ARE HAZARDOUS ANTI-DIARRHOEALS

1. Drug Formulations containing Chloramphenicol and Streptomycin.

2. Common Brands :

   Chlorostrep, Enterostrep, Streptoparaxin, Ifistrep, Streptachlor; Intestostrep, Cilastrep, Basiplon, Glucostrep, et.c etc.

3. Used and propagated for :

   All sorts of diarrhoeas.

4. Why irrational and unscientific :

   a) Chloramphenicol is a drug for Typhoid fever. No text book of medicine or pharmacology recommends its use in diarrhoea of any kind. Majority (more than 90%) cases of diarrhoea do not require any drug except rehydration solution. Use of drugs in diarrhoea prolongs the disease without any benefit whatsoever.

   b) Streptomycin is not absorbed when given by mouth. Therefore, it is not effective in diarrhoea. Text Books do not recommend its use in this condition.

5. Why hazardous :

   Use of Chloramphenicol is associated with the development of a fatal blood disease (A plastic anaemia). It may be necessary to take the risk when we have to use the drug in Typhoid fever. However there is no justification in taking the risk by using the drug in diarrhoea where it has absolutely no benefit.

   b) Frequent use of antibiotics for brief periods leads to drug resistance which may be responsible for epidemics of gastroenteritis and Typhoid fever.

Streptomycin is a drug of choice in treatment of tuberculosis and should generally be reserved for this use because when used in the treatment of other bacterial infections; resistance has been found to develop within 2-3 days.

- Martindale, 28th Edn., 1982
The Extra Pharmacopia.

6. Alternatives :

1. Safe water supply (not only drinking water).
2. Use of oral Rehydration salts. (See Annex. 6.3 & 6.4)
3. Cotrimoxazole when needed.
4. Paromomycin
5. Diluxanide

7. Banned in which country :

Bangladesh has banned all preparations like Chlorostrep. In most countries ot the world these are not banned because such drug formulations were never allowed to be marketed in these countries.

It should be noted that -

* The Drug Consultative Committee in 1980 had recommended weeding out of Chloramphenicol-Streptomycin Combination.

* The combination is considered irrational and is not even mentioned in several medical text books.

* It is openly sold in India - under false claims of safety and reliability.

C

EXAMPLE OF HAZARDOUS DRUG COMBINATION

FACTS SHEET: E.P. DRUGS

(High Dose Estrogen Progesterone Combination)

1976	Warning by WHO against the use of high dose Estrogen - Progesterone combination drugs for hormonal pregnancy testing.
1979	Dr. Palanniappan's study in Kilpauk Medical College showed that mothers of 31% of children born malformed had taken high dose EP drugs during their pregnancy.
1982	EP Education campaign launched by health, consumer and women's groups.
	High dose EP drugs banned under D.O. No.X19013/8/81-D Drug Controller of India banning manufacture from 31.12.82 and sales from 30.6.83.
	against the drug ban from Calcutta and Bombay High Courts.
1986	EP Drugs still widely misused for pregnancy testing, including abortion and menstrual disorders etc. Even through indications written in English in some of the package inserts says "Secondary ammenorrhea' i.e. for stopping of periods. Most of these drugs are brought over-the-counter without warning or prescribed for pregnancy testing and inducing abortions. There does not exist any systematic effort in monitoring the drug utilization patterns in the field while market surveys are done by drug companies to help them in their marketing, the extent of misuse, nature of misuse is nobody's business. With a weak drug control mechanism such non-monitoring is a health hazard.

The Stay orders have still not been challenged by the health authorities nor have they been revoked by the Courts. Ironically, Organon is not allowed to market high dose EP drugs in its parent country i.e. The Netherlands.

D

EXAMPLE OF HAZARDOUS DRUG COMBINATION

ANALGIN - THE HAZARDOUS PAINKILLER

Analgin is the most commonly used analgesic available as Novalgin and others. It can cause fatal agranulocytosis which is a marked reduction of white blood cells in the blood and bone marrow. Most of the advanced countries have discarded analgin long back, but it continues to be manufactured by our public sector undertakings. Leading haematologist Dr. B.C. Mehta has reported many fatal cases of analgin-induced agranulocytosis. He strongly believes that analgin should be banned.

Two or more analgesics added together do not give additional benefits. On the contrary the mixtures are likely to give rise to undesirable side effects.

We have many combinations with analgin e.g.

Analgin + propoxyphene

Andex, Walagesic etc.

Analgin + antispasmodic

Baralgan, Codolsic, Spasmizol etc.

Analgin + Paracetomol

Promalgin, Ultragin, Zimalgin etc.

Analgin + Phenylbutazone

Esgipyrin etc.

Analgin + Oxyphenbutazone

Oxalgin, Kilpane etc.

ANALGIN/ANALGINUM/DIPYRONE/ METAMIZOL/NORAMIDOPYRINE METHANESULFONATE SODIUM/METHAMPYRONE/ SULPYRINE

Brand	Manufacturer
Aareigin	Ramsons
Adgesic	Ethico
Adol	Acila
Algesin-O	Alembic
Algeril	P&B Labs
Supraigin	Sarvodaya
Synalgesic	G. Manners
Tnalgin-D	Osseisule
Trigerzin	Trigger
Trigin	Biox
Tromalgin	La Pharma
Trypin	Healer
Tunogyn	Kee Pharma
Ultragin	G. Manners
Uniprox	Unicure
Vespanil	Veco
Virgonalgin	Virgo
Wespalgin	West Coast
Zimalgin-A	Rallis
Zinalgin	TCF
Zonalgin	Fedro
Paranalgin	Gavert
Par Analgin	Bombay Tablets
Parazoil	Ganesh
Paraladim	Fourts
Penalfine	La Pharma
Penalgin	Terachem
Petragin	Thio Pharma
PFI	Medi
PRC	Alkem
Prednphenol-6	Gavert
Primdnl	Prim
Promalgin	Uniloids
Pvragesic	Jamsons
Quikalgin	Svnthiko
Quikalgin	Thio-Kof
Reterin	MacMOHAN
Repalgin	Ravs
Resin	Assam Pharma
Ricotast	Plazma
Rumalgin	Shree
Rumasol	Excel
Rupalgin	Rup
Sedvn-A-Forte	M.M. Labs
Selectagesic	Supreme
Shormetal-D	Themis
Spalcin	Martel Hammer
Spanil	Grosons
Spasaron	Kon Test
Spasmatac	ATaCC
Spasmate	Terce
Spasmizol	IDPL
Spasmlan	Adore
Spasmo	Enkay
Spasmo-Amidazone	Suprachem
Spasmolysin	Standard
Spasmogin	Indochem
Starcygin	Star
Sterpose A.N.	Steriil
Sunalgin	Medinex
Alpox	Alps
Anadex	Concept
Anacet	Semit
Analag	ATaCC
Analgin	AArge
Analgin	Acila
Analgin	Alembic
Analgin	Alkem
Analgin	Allied Pharma
Analgin	Alma
Analgin	Alpha Drugs
Analgin	Alpine
Analgin	Associated Products
Analgin	ATaCC
Analgin	Belco
Analgin	Borachem
Analgin	BP Labs
Analgin	Chemitech
Analgin	Comet
Analgin	Cooper Pharma
Analgin	Curewell
Analgin	Cyper
Analgin	DCI
Analgin	Dev's
Analgin	Drugs India
Analgin	DWD
Analgin	Emcee
Analgin	Entod
Analgin	Eros
Analgin	Fairdeal
Analgin	Febro
Analgin	Forstar
Analgin	Gavert
Analgin	Glyco Labs
Analgin	Haffkine
Analgin	Hima Research
Analgin	H. Jules
Analgin	ICCO
Analgin	IDPL
Analgin	INDC
Analgin	Indian Health
Analgin	Indus Pharma
Analgin	Inga
Analgin	International
Analgin	Kab Pharma
Analgin	Kanpha
Kanopar	Kanpha
Kapaxgin	Kaptab
Kaptragin	Kaptab
Kelgin	Kee Pharma
Kepoxgin	Kanpha
Kil pane	Biddle Sawver
La-Pyrin	La Pharma
Largesic	Lark
Medalgin	Medoz
Maxigesic	Ethico
Metabutadec	Supreme
Metamizole	Stamac
Metoxvl	Actwell
Micron Plus	Wesco
Molgin	Dia Pharma
Analgin	North Bengal
Analgin	Mercury
Analgin	Novochem
Analgin	NuLife
Analgin	Nymph
Analgin	Paam
Analgin	Panacea
Analgin	Pan Pharma
Analgin	Paras
Analgin	PCI
Analgin	Pharmakab
Analgin	Prakash
Analgin	Pulvmar
Analgin	Radicura
Analgin	Reason
Analgin	Ravs
Analgin	Remedia
Analgin	Remedies India
Analgin	R.P. Drugs
Analgin	Sain
Analgin	South (I)
Analgin	Sitis-Hyd.
Analgin	Stamac
Analgin	Star
Analgin	Tablets
Analgin	Taracnem
Analgin	TeeCee
Analgin	Tuton
Analgin	White-Way
Analpar	Thio-Kof
Anamol	Heiko
Anapas	Western
Anapiron	Roc
Anmol	Medirose
Anoxy	West Coast
Avalgin	Tarachem
Avalortan	Khandewal
Baralgan	Hoechst
Belgin	Belco
Benalgis	Franco-Indian
Biogin	Bio-Med
Bitalgin	Bombay Tablet
Buscopan Comp	German
Butacortindon	Indon
Butagin	Alkem
Butagin	Tablets
Butaphen Plus	Biochem
Butaster	West Coast
Monalgin	Monokem
Mvalgin	Shree
Mvlogin	Chemical & Phar.
Narcogin	Somatico
Narogene	Anglo-French
Neorin	Themis
Nivelgin	Nectarine
NOVALGIN	Hoechst
Novapam	Febro
Nurolgit	Nulife
Nycin	Nymph
OAD	Amee
Orphalgin	Biddle Sawver
Canapar	US Vitamin
Capagin	Kon Test
Cartagin	Indochem
Celgal	Veco
Cemizole	IDPL
Cetolgin	N.I. Pharma
Cetalgin-D	Optino
Cetogin	Surchem
Codolsic	FDC
Dadhalgin	Dadha
Dexabutalgin	Monokem
Dexalgin Plus	Lenec
Diapar	Navil
Dicigesic-N	DCI
Dicolgin	Kanpha
Dipralgin	PCI
Dizalgin	Franklin
Dolagin	Pharmed
Dolo-Neurobin	Merck
Doloril-A	Indico
Dolotame	Somatico
Dolotril	Saima
Doloxan	Shree
Doloxene	Swastik
D-Pyrone	B.P. Labs
Dublactin	Tablets
Duogesic	Sanderson
Dypalgin	P&B Labs
Ebijlam	Ebers
Epagin	Kon Test
Esgipyrin	S.G. Pharma
Eucrasil	Eisen
Fargesic	Phar-East
Fevozone	Alpha
Flunil	Excel
Gavalgin	Gavert
Geecoprin	Paam
Ginol	Nibin
Histann	La Pharma
Iccalgin	ICCO
Indalgin	Indus
Indo-Analgin	Indochem
Inflagin	Kanpha
Inflar	Navil
Jemjesic	Jems
Kanamol	Kent
Oxal	Dia Pharma
Oxalgin	Cadila
Oxan-V	Vigma Labs
Oxigin	Min
Oxvdigin	Oasis
Oxvdril-DS	Dvnamic
Oxvmol	Bio Med
Oxvnal	Euphoric
Oxvpose	Sims
Oxypyron	Thio-Pharma
Oxvzol	Medirose
Palgin	Chemo Pharma
Pamagin	Alkem
Pamolgin	Paam
Paralgenol	Veco
Paragesic	Radicals
Paralgicin	Staochem
Paralgin	Emcee
Paralgin	Godama
Paralgin	Stamac

Analgin even when allowed in other countries is NEVER used as the drug of first choice but used only in restricted conditions when other analgesics cannot be used.

Aspirin, inspite of numerous new painkillers, flooding the market is still considered the most effective and relatively safe.

Market Size : Retail trade market in 1983 - Rs.17.02 crores.

E

EXAMPLE OF IRRATIONAL DRUG COMBINATION

COUGH SYRUPS - A CONTRADICTION

TITLE	:	Cough Syrups; Expectorants
COMMON BRANDS	:	Avil Expectorant, Benadryl expectorant, Cadistin expectorant, Cheston, Corex, Coseopin, Cosome, Deacos, Dilosyn expectorant, Driostan expectorant, Grilincutus, kanaka, Phensedyl, Piriton expectorant, Tixylix, Zeet expectorant, etc. etc.
USED & PROPAGATED FOR	:	All sorts of cough.
WHY IRRATIONAL	:	These cough syrups are mixtures of drugs which stimulate coughing (Ammonium Chloride, Ipecac, etc), as well as those which suppress coughing (codeine, Noscapine etc.) and antihistamines that dry the secretions (Benadryl, Piriton, Avil etc). Coexistence of such drugs in a syrup is absolutely unscientific and irrational. Coughing is a protective activity of the body. It should not be suppressed except in certain conditions. In these cases, single ingredient cough suppressants (like codeine, Dextromethorphan etc.)should be used. Thereis absolutely no scientific basis for using cough suppressants and cough stimulants together. Notext book of medicine or pharmacology recommends the use of such drug formulations.

WHY HAZARDOUS	:	Prolonged use of cough syrups is habit forming; may cause stomach upsets; reduce food intake, and cause drowsiness. It is dangerous to drive or work near fire after taking cough syrups because a large number of them contain antihistaminic drugs. Chloroform, present in many of these cough syrups, may damage the liver and may even cause cancer.
ALTERNATIVES	:	Coughs need not be suppressed always. Simple steam inhalation is advisible for coughing. If at all any drug is to be used for cough, it should be a single ingredient drug formulation.
BANNED IN WHICH COUNTRY	:	Bangladesh has banned all cough syrups and combinations.
MARKET SIZE	:	Retail Trade Market in 1985-Rs.35.20 crores.

No cough syrups or cough Lozenges have been included in the WHO essential drug list.

(Technical Report Series 615, 641, 685 or 722).

F

EXAMPLE OF IRRATIONAL DRUG COMBINATION

TONICS - ARE A WASTE

TITLE	:	Tonics; Health Restoratives.
COMMON BRANDS	:	Bayer's Tonic, B-G-Phos, Neogadine Elixir, Orheptal, Ranbaxy's Tonic, Santevini, Dexorange, Toniazol, Hepatoglotin, etc.
USED AND PROPAGATED FOR	:	Debility, Chronic diseases, loss of appetite, restorative, weight loss, fatigue, etc.
WHY IRRATIONAL	:	What is needed in the above cases is an adequate mixed diet and not tonics which are mixtures of B-complex vitamins in solutions of sugar and alcohol. None of the above cases can be cured by vitamins. Persons taking adequate mixed diet containing leafy vegetables do not suffer from vitamin deficiency. Moreover, if vitamin deficiency occurs, it is to be treated by supplying the specific vitamin which is deficient, and it should be taken in dry, tablet form. If vitamins are taken as tonics it is only more costly. No medical textbook recommends the use of tonics.

WHY HAZARDOUS	:	Consumption of B-Complex vitamins as tonics may not be hazardous as such, but other substances like caffeine, strychnine, Leptazol etc. present along with it are potentially harmful. Regular intake of excess of vitamin A and D is hazardous.
ALTERNATIVES	:	Adequate mixed diet, specific vitamin deficiency cases should be treated with specific vitamins in dry form.
BANNED IN WHICH COUNTRY	:	Tonics and health restoratives are banned in Bangladesh, U.K. does not regard tonics as drugs.
MARKET SIZE	:	Rs. 36 crores in the retail trade in 1985.

Hazardous Drugs

DELHI Patriot 4.12.84

Harmful drugs flourish in India

Certain harmful drugs which have been banned in Nepal, Bangladesh, Sri Lanka, Pakistan and Malaysia are still being administered to patients in India, according to a medical expert from Bangladesh, reports PTI.

Citing the example of analgin (amidopyrine), Dr Zafarullah Chowdhury, director of [illegible]

Cacutta THE TELEGRAPH 15 December 84

'40% drugs on sale harmful'

INDIAN EXPRESS, NEW DELHI 8.7.82

Drug to determine pregnancy harmful

BOMBAY, March 7 (PTI).

In a report coinciding with the International Women's Day on Monday the Centre for Education and Documentation (CED) here has urged women not to use the hormone drug - estrogen - progestrone—to determine pregnancy, as it could induce foetal abnormalities and malformations and sometimes even cause termination of pregnancy.

BOMBAY The Sunday Obs. 22.12.85

Two-thirds of the drugs are useless or harmful'

[illegible] been produced in sufficient quantities. While 40,000 Indians

DELHI Patriot 4.12.85

Harmful drugs being used in India: expert

NEW DELHI, Dec 3 (PTI).

Certain harmful drugs which have been banned in Nepal Bangladesh, Sri Lanka, Pakistan and Malaysia are still being administered to patients in India according to a medical expert [illegible]

THE ECONOMIC TIMES 5.12.84

Harmful drugs still in use in India

NEW DELHI, December 4.

Certain harmful drugs which have been banned in Nepal, Bangladesh, Sri Lanka, Pakistan and Malaysia are still being administered to patients in India, according to a medical expert from Bangladesh, says PTI.

INDIAN EXPRESS, NEW DELHI 5.1.85

'Harmless' drugs not so harmless

By PUSHPA GIRIMAJI
Express News Service

NEW DELHI, Jan 4.

Absence of adequate information and education on the side effects and contraindications associated with what are considered harmless analgesic drugs or "over the counter" drugs available without a doctor's prescription, the Drugs and Cosmetics Act, so as to make it compulsory for manufacturers to provide detailed information on the wrappers. Such a step, the Centre pointed out, would prevent wrong usage of the drug.

To underscore the inadequacy of the information provided on these drugs of common usage, the Centre mediately: do not use the drug for [illegible] haemorrhagic states, under treatment of diabetics, asthma or gout, undergoing surgery within a week, pregnant women.

Warnings associated with the use are: keep out of reach of children; if anybody, especially children, take overdose, get medical help immediately; do not use the drug for [illegible] paracetamol can be used for [illegible] children.

Tablets containing both aspirin and [illegible] to four times a day, when required children in the age group of six to [illegible] years—half to one tablet, three to four times a day, below one year [illegible] be given under medical supervision daily dose should not exceed 1-2 g.

STATEMENT SHOWING THE CATEGORIES OF FIXED DOSE COMBINATIONS RECOMMENDED BY THE SUB-COMMITTEE OF THE DRUGS CONSULTATIVE COMMITTEE FOR BEING WEEDED OUT (1980)

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A. Categories of fixed dose combinations to beweeded out immediately.

CATEGORY	REASONS FOR WEEDING OUT
1. Fixed dose combinations of Steroids	Fixed dose combinations of staroids with any other category of drugs should not be allowed as they are considered harmful for the following reasons:- (a) The adrenal suppression accompanying steroid therapy leads to symptoms and signs of adrenal insufficiency, if the steroid is abruptly withdrawn. (b) It is difficult to titrate the dose of the steroid when it is present in fixed dose combinations with other drugs.
2. Fixed Dose Combinations of Ami-dopyrine	Ami dopyrine is considered toxic because:- (a) It causes high incidence of agranulocytosis. (b) In some individuals, it may cause a sharp fall of total leueocyte count associated with chill, fever, headache and pain in muscles and joints following the administration of drug.
3. Fixed Dose Combinations of Chloramphenicol	Fixed Dose combinations of Chloramphenicol with any other category of drugs is considered harmful for the follwing reasons and should not be allowed :- (a) Chloramphenicol is the commonest drug which causes pancytopenia and peripheral blood changes including Leucopenia, Thrombocytopenia and aplasia of the boen marrow. This reaction si not related to dose and when done, marrow aplasia is complete; the fatality rate is almost 100%

(b) Patients receiving chloramphenicol must be checked repeatedly for blood studies which is however generally done in the case of patients receiving fixed dose combinations of Chloramphenicol.

4. Fixed Dose Combinations of Ergot

Fixed dose combinations of Ergot should not be allowed. Such combinations are considered harmful for the following reasons:

(a) They may cause uncontrollable bleeding and may lead to serious consequences.

(b) They may cause many harmful side effects.

5. Fixed Dose combinations of Vits. with anti-inflammatory Agents & Tranquilizers

Fixed dose combinations of Vits. with anti-Inflammatory agents and tranquilizers should not be allowed. Such combinations are considered irrational for the following reasons:

(a) There is no definite role of Vitamins in the management of inflammatory disorders and therefore a fixed dose addition of Vitamins in such preparation will be rational.

(b) Similarly there is no rationale for adding Vitamins to tranquilizers.

6. Fixed Dose combinations of Atropine in Angles Anti-pyreties.

Fixed dose combinations of antropine in analgesic antipyretic should not be allowed as atropine may reduce efficiency of antipyretics by blocking sweating response.

7. Fixed Dose combinations of Analgin

Fixed dose combinations of any category of drug with analgin in oral dosage form are considered generally harmful as analgin is potentially a toxic drug and may cause agranulocytosis except for some combinations which may have therapeutic rationale e.g. with neurovitamins. However, fixed dose combinations with analgin in injectable form may be continued to be allowed as these are generally meant to

combat an acute attack of pain, and injectables are less likely to be misused.

8. Fixed Dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins

Fixed dose combinations of Yohimbine and Strychnine in a formula containing Teststerone and Vit.B. 12 should not be allowed. Such combinations are considered harmful and irrational for the following reasons:

(a) Yohimbine easily penetrates gthe ONS and can cause central excitation including rise of B.P. and heart rate, hyperexcitability and tremour.

(b) There is no convincing evidence regarding the aphrodisiac effect of Yohimbine and the drug has no proven therapeutic values.

(c) There is no rational basis for the use of strychnine in therapy and therefore no justification for the use of it in any proprietory medicine.

(d) There is a very narrow margin between the therapeutic dose and the toxic dose of strychnine.

9. Fixed dose combinations of Iron with Strychnine Arsenio, Yohimbine

Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine should not be allowed as there is no rationale of such combinations and such a combination can cause harmful side effects.

10. Fixed dose combination of Sodium Bromide/Chloral Hydrate with other drugs

Fixed dose combinations of Sodium Bromide/Chloral Hydrate with any category of drug are considered irrational and harmful for the following reasons :

	Use of both Sodium Bromide and Chloral Hydrate have become obsolete as there safer hypnotic drugs available today and their therapeutic concentration in blood is very close to their toxic levels.
11. Fixed dose combinations of Tetracycline, Analgin with Vitamin C	Fixed dose combinations of Tetracycline, Analgin, etc. with Vit. C should not be allowed as there is no rationale of such combinations.
12. Fixed dose combinations of Ayurvedic drugs with modern drugs	Fixed dose combinations of Ayruvedic drugs and potent allopathic drugs like Stilboestrol could be very harmful and there is no adequate evidence of safety of the interaction of drugs of these gtwo systems of medicine.
13. Fixed dose combinations of Phenacetin	Fixed dose combinations of any category of drugs with Phenacetin should not be allowed, as the question of banning Phenacetin because of its potential toxicity (nephropathy, methemoglobinemea, hemolytic anemia as a consequence of chronic over dosage) is under active consideration of the Government.
14. Fixed dose combinations of Chloramphenicol with Streptomycin	Fixed dose combinations of Chloramphenicol with Streptomycin should not be allowed as Chloramphenicol being potentially a toxic drug its use should be kept restricted to enteric fever only.
15. Fixed dose combination of Penicillin with Streptomycin	Fixed dose combination of penicillin with streptomycin should not be allowed.
16. Fixed dose combinations of more than one anti-histaminics	Fixed dose combinations of more than one anti-histaminics in oral dosage form should not be allowed as the differences between their action is but marginal.

B. Categories of fixed dose combinations to be weeded out over a specified time.

CATEGORY	REASONS FOR WEEDING OUT
1. Fixed dose combinations of Anti-histaminics in anti-diarrhoeals	Fixed dose combinations of sedative anti-histaminics in anti-diarrhoeal preparations may be permitted provided all ingredients are in adequate therapeutic doses.
2. Fixed dose combinations of Penicillin with Sulphonamides	Fixed dose combinations of penicillin with sulphonamides are irrational for the following reasons : (a) The combination of penicillin, a bactericidal drug and sulphonamide, a bacteriostatic drug may cause antagonism. (b) There is risk of development of bacterial resistance to both the drugs.
3. Fixed dose combinations of anti-histaminic with tranquilizer	Fixed dose combinations of anti-histaminics having patent sadative preparations (for example, diphenhydramine dimenhydrinate, tripelennamines, pyrelamine, Antazolin methapyrilline, etc). with tranquilizers are considered irrational for the following reasons : Such combinations may cause enhanced sedation, which may interfere with the patient's day time activity and dull the mind and slow the reflex activity.
4. Fixed dose combinations of tranquilizers, Anti-Histaminics and Analgesics	Fixed dose combinations of Tranquilizers with anti-histaminics and analgesics in oral dosage form are considered irrational for the following reasons : (a) Such combinations may cause a lot of unwanted sedation, which may interfere with the patient's day time activity and dull the mind and slow reflexes.

(b) There may not be many clinical situations which would need a fixed dose combination of these three categories of drugs and there will be unnecessary drugging. However, fixed dose combinations of these drugs in injectable form may be allowed as injectables are not likely to be misused.

5. Fixed dose combinations of Vitamins with Analgesies

Fixed dose combinations of high dose Vitamins with analgesics should not be allowed unless there is adequate evidence in support of the rationale of such combination.

6. Fixed dose combinations of Paracetamol with Anti-histaminics and tranquilizers

Fixed dose combinations of Paracetamol with anti-histaminics and tranquilizers should not be allowed as there is hardly any clinical situation which should demand a fixed dose combination of anti-pyretic, an anti-histaminic and tranquilizer. However, fixed dose combinations of paracetamol with anti-histaminics and paracetamol with tranquilizers may be allowed provided the formula contains an adequate dose of such ingredients.

7. Fixed dose combinations of prophylactic Vitamins in anti-TB Drugs

Fixed dose combinations of Vitamins in prophylactic doses in anti-TB drugs should not be allowed as such combinations lack rationale. However, combinations having a therapeutic rationale such as INH + B6 may be allowed.

Bangladesh - Drug Policy

Criteria for recommended withdrawal of products from the Bangladesh market

The Expert Committee constituted by government Order No. S-DA/D-D-20/82/74 dated 27 April 1982 met at 10.00 a.m. on 28 April 1982 in the office of the Director, IPGMR, Dacca, under the Chairmanship of Professor Nurul Islam for evaluation of the pharmaceutical products available in the country and to draft a National Drug Policy, keeping in view the health needs of the country.

Consistent with the declared guidelines of Government to provide basic needs of life to the majority of the people through austerity, and to improve the economy of the country and prevent wastage of foreign exchange, the production and/or importation of unnecessary drugs or drugs of marginal value have to be stopped.

Almost any drug may produce unwanted or adverse reactions. The combination of two or more active ingredients not only makes the product costlier, it also increases the possibility of adverse reaction without increasing the efficacy over a single ingredient product. Hence, as a general rule, combinations of similar or disimilar drugs will be prohibited.

Combination drugs could be approved if the drug company can give definitive, approved scientific proof (ie WHO publications, British National Formulary, British Pharmacopeia, European Pharmacopeia, USA or other authoritative guidelines like Goodman's and Gilman's 'The Pharmacological Basis of Therapeutics', 'Current Medical Diagnosis and Treatment', etc.) of the drugs' synergistic action and increased efficacy. They

also have to prove conclusively that combining the elements creates no increase of toxicity or side effects nor instability of the compound or shortening of the life of the product.

One of the greatest sources of drainage of the country's financial resources is the irresponsible prescribing and marketing and inappropriate self-use of vitamins. Another great wastage of meagre resources is cough mixtures, gripe water, alkali preparations, and digestive enzymes which are of little or no therapeutic value.

It is unanimously decided that the following criteria will serve as the guidelines in evaluatiing all the registered/licensed pharmaceutical products manufactured and/or imported in Bangladesh.

i. The combination of an antibiotic with another antibiotic or antibiotics with corticosteroids or other active substances will be prohibited.

Antibiotics harmful to children (eg Tetracycline) will not be allowed to be manufactured in liquid form.

ii. The combination of analgesics in any form is not allowed as there is no therapeutic advantage and it only increases toxicity, especially in the case of kidney damage. The combination of analgesics with iron, vitamins or alcohol is also not allowed.

iii. The use of codeine in any combination form is not allowed as it causes addiction.

iv. In general, no combination drugs will be used unless there is absolutely no alternative single drug available for treatment or if no alternative single drug is cost effective for the purpose.

Certain exceptions will be made in the cases of eye, skin, respiratory and haemorrhoidal preparations, co-trimoxazole, oral rehydration salts, antimalarial, iron-folic, etc., as well as certain vitamin preparations, allowing combinations of more than one active ingredient in a product.

v. Vitamins should be prepared as single ingredient products with the exception of B complex. Members of vitamin B complex with the exception of B12 may be combined into one product. B12 always has to be produced as a single ingredient injectable product. Other members of B complex may also be produced as single ingredient products (eg B1, B2, B6 etc.). Vitamins will not be allowed to be combined with any other ingredient such as minerals, glycerophosphate, etc. It will be allowed to produce vitamins in tablets, capsules and injectable form only.

No liquid forms will be permitted because of wastage of financial resources and the tremendous misuse involved. However,

paediatric liquid multivitamin (with no B12, E, K and/or minerals) will be allowed to be manufactured in bottles of up to 15 ml. size with droppers. Paediatric liquid preparations of single ingredient vitamins will also be allowed to be manufactured in bottles of up to 15 ml. with droppers.

vi. No cough mixtures, throat lozenges, gripe water, alkalis, etc. will be allowed to be manufactured or imported as these are of little therapeutic value and amount to great wastage of our meagre resources.

vii. The sale of tonics, enzyme mixtures/preparations and so-called restorative products flourish on consumer ignorance. Most are habit-forming and with the exception of pancreatin and lactase these are of no therapeutic value. Henceforth local manufacture or importation of such products will be discontinued. However, pancreatin and lactase will be allowed to be manufactured and/or imported as single ingredient products.

viii. Some drugs are being manufactured with only a slight difference in composition from another product but having similar action. This only confuses both patients and doctors. This will not be allowed.

ix. Products of doubtful, little or no therapeutic value and rather sometimes harmful, are subject to misuse and will be banned.

x. All prescription chemicals and galenical preparations not included in the latest edition of British Pharmacopeia or British Pharmaceutical Codex will be prohibited.

xi. Certain drugs, in spite of known serious side-effects and possibility of misuse, having favourable risk-benefit ratio may be allowed to be produced in limited quantity for restricted use. These will be prescribed by specialists only.

xii. The same or close substitutes of a drug which is being produced in the country will not be allowed to be imported, as a measure of protection for the local industry. However, if local production is far short of needs, this condition may be relaxed.

xiii. A basic pharmaceutical raw material which is locally manufactured will be given protection by disallowing it or its substitute to be imported if sufficient quantity is available in the country.

xiv. The role of multinationals in providing medicines for this country is acknowledged with appreciation. In view of the calibre of machinery and technical know-how which lies in their hands for producing important and innovative drugs for the country, the task of producing antacids and vitamins will lie

solely with the National Companies, leaving the Multinationals free to concentrate their efforts and resources on those items not so easily produced by smaller National Companies. Multinationals will, however, be allowed to produce injectable vitamins as single ingredient products.

xv. No foreign brands will be allowed to be manufactured under license in any factory in Bangladesh as this leads to unnecessary high prices and payment of royalties. In the light of this policy, all existing licensing agreements should be reviewed.

xvi. No Multinational Company without their own factory in Bangladesh will be allowed to market their products after manufacturing them in another factory in Bangladesh on toll basis.

– After approval of these recommendations by Government, the licensing authority for drugs (Director, Drug Administration) will have to issue necessary orders withdrawing/cancelling the licensing/registration of the products, with the provision of a maximum period of six months grace for using up the present stock of corresponding raw materials. Henceforth no raw materials should be allowed to be imported for the manufacture of these products. All future licensing registration should be given after evaluation of the products on the basis of the above criteria.

VII

COMPARISON OF PREVIOUS RECOMMENDATIONS WITH THE GAZETTE NOTIFICATION OF JULY 1983

The serial numbers of the three lists i.e. DCC, DTAB and Gazette notification differs as it pertains to each individual list on attempt at drawing up a comparison of the above mentioned lists. So that the Steroid Ban is dealt with No. (i) of DCC; (15) of DTAB and (14) of the Gazette Notification. Where. DCC list has been kept as the baseline.

Recommended by sub-Committee of Drug Consultative Committee: be weeded out immediately, 1980.	Drug Technical Advisory Board Report, 25 May 1982	Gazette Notification of Drug Controller of India July 23, 1983. No. X 11014/1/83.
1. *Fixed dose combination of Steroids*	15. *Fixed dose combinations of steroids for internal use except combinations of steroids with other drugs for treatment of asthma.*	14. *Fixed dose combinations of steroids for internal use except combinations of steroids with other drugs for treatment of asthma.*
2. *Fixed dose combinations of amidopyrine*	1. *Fixed dose combinations of amidopyrine.*	1. *Amidopyrin (restriction dose combination lifted)*
3. *Fixed dose combinations of chloramphenicol.*	16. *Fixed dose combinations of chloramphenicol except preparation of chloramphenicol and streptomycin.*	15. *Fixed dose combinations of chloramphenicol for internal use except combinations of chloramphenicol and streptomycin.*
4. *Fixed dose combinations of Ergot.*	17. *Fixed dose combinations of Ergot except combinations of its alkaloid ergotamine with caffeine.*	16. *Fixed dose combinations of Ergot.*
5. *Fixed dose combinations of Vitamins with anti inflammatory agents and tranquillizers.*	2. *Fixed dose combinations of vitamins with anti inflammatory agents and tranquillizers.*	2. *Fixed dose combinations of vitamins with anti inflammatory agents and tranquillizers.*
6. *Fixed dose combinations of atropine in analgesics and anti pyretics.*	3. *Fixed dose combinations of atropine in analgesics and anti pyretics.*	3. *Fixed dose combinations of atropine in analgesics and anti-pyretics.*
7. *Fixed dose combinations of analgin.*	*(Excluded)*	*(Excluded)*
8. *Fixed dose combinations of yohimbine and strychnine with testosterone and vitamins.*	5. *Fixed dose combinations of yohimbine and strychnine with testosterone and vitamins.*	5. *Fixed dose combinations of yohimbine and strychnine with testosterone and vitamins.*
9. *Fixed dose combinations of iron with strychnine, arsenic and yohimbine.*	6. *Fixed dose combinations of iron with strychnine, arsenic and yohimbine.*	6. *Fixed dose combinations of iron with strychnine, arsenic and yohimbine.*
10. *Fixed dose combinations of sodium bromide/chloral hydrate with other drugs.*	7. *Fixed dose combinations of sodium bromide / chloral hydrate with other drugs.*	7. *Fixed dose combinations of sodium bromide / chloral hydrate with other drugs.*
11. *Fixed dose combinations of tetracycline, analgin with vitamin C.*	13. *Fixed dose combinations of tetracycline with vitamin C (combination with analgin excluded.)*	12. *Fixed dose combinations of tetracycline with vitamin C.*
12. *Fixed dose combinations of ayurvedic drugs with modern drugs.*	8. *Fixed dose combinations of Ayurvedic and Unani drugs with modern drugs.*	*(Excluded)*
13. *Fixed dose combinations of phenacetin.*	9. *Fixed dose combinations of phenacetin.*	8. *Phenacetin.*
14. *Fixed dose combinations of chloramphenicol with streptomycin.*	*(Excluded)*	*(Excluded)*
15. *Fixed dose combinations of penicillin with streptomycin.*	*(Excluded)*	*(Excluded)*
16. *Fixed dose combinations of more than one antihistaminics*	*(Excluded)*	*(Excluded)*

Recommended by sub-Committee of Drug Consultative Committee: 1980.	Drug Technical Advisory Board Report, 25 May 1982	Gazette Notification of Drug Controller of India July 23, 1983. No. X 11014/1/83.
To be weeded out over a specified time		
1. *Fixed dose combinations of anti-histaminics in anti-diarrhoeals.*	10. *Fixed dose combinations of anti-histaminics with anti-diarrhoeals.*	9. *Fixed dose combinations of anti-histaminics with anti-diarrhoeals.*
2. *Fixed dose combinations of penicillin with sulphonamides.*	11. *Fixed dose combinations of penicillin with sulphonamides.*	10. *Fixed dose combinations of penicillin with sulphonamides.*
3. *Fixed dose combinations of anti-histaminics with tranquillizers.*	*(Excluded)*	*(Excluded)*
4. *Fixed dose combinations of tranquillizers, anti histaminics and analgesics.*	*(Excluded)*	*(Excluded)*
5. *Fixed dose combinations of vitamins with analgesics.*	12. *Fixed dose combinations of vitamins with analgesics.*	11. *Fixed dose combinations of vitamins with analgesics.*
6. *Fixed dose combinations of paracetamol with anti-histaminics and tranquillizers*	*(Excluded)*	*(Excluded)*
7. *Fixed dose combinations of prophylactic vitamins in anti TB drugs except INH with vitamin B6.*	18. *Fixed dose combinations of prophylactic vitamins with anti TB drugs except combination of INH with vitamin B6.*	17. *Fixed dose combinations of vitamins with anti TB drugs except combination of Isoniazide with Pyridoxine Hydrochloride (Vitamin B6)*
	Additions to DCC List :	
	4. *Fixed dose combinations of strychnine and caffeine in tonics.*	4. *Fixed dose combinations of Strychnine and caffeine in tonics.*
	14. *Fixed dose combinations of hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery.*	13. *Fixed dose combinations of hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery and for external use only.*
		Additions to DTAB List :
		18. *Penicillin skin/eye ointment.*
		19. *Tetracycline liquid oral preparations.*
		20. *Nialamide*
		21. *Practolol*
		22. *Methapyrilene, its salts.*
		Addition to Gazette Notification 1984
		23. *Methaqualone*
		24. *Oxytetracyline Liquid Oral Preparations*
		25. *Demeclocycline Liquid Oral Preparations*
		Addition to Gazette Notification 1985
		26. *Combination of Anabolic Steroids with other drugs.*

Compiled by

Voluntary Health Association Of India
From Government & Gazette Notification

VII.

DRUG INFORMATION AND ETHICAL MARKETING

Perhaps the most crucial component of a rational drug policy is to ensure that accurate and unbiased information about drugs is available to consumers and to medical practitioners. The manufacturers have the primary responsibility of making such information available in respect of the drugs produced by them. This is the area where there is maximum confusion. There is ample evidence to show that drug producers as a rule either suppress vital information relating to their products, or deliberately provide wrong information.

The situation prevailing in India in this regard is truly incomprehensible. A glaring example is provided by the recent case of the judgement of the Kerala High Court on writ petition No. OP 8439/1982 in which the Court directed the Central and State Drug Control Authorities "to publish the list of trade/brand names and the names of the manufacturers of (these) drugs" (which have been banned). This directive has not been complied with, on the excuse that the drugs have been licenced and registered with State health authorities and the Centre has no clue about the various formulations and brand involved.

The current practice is to notify the banning of a drug through a Gazette Notification. Surprisingly, the Gazette Notification indicates the generic name of the drug whichare being banned, whereas the products are all marketed under trade names. Moreover, the notifications are generally couched in such ambiguous language that it is normally impossible to gather whether the ban becomes applicable if any one of the drugs in the general category is present in a combination, or whether all the drugs have to be present in combination for the ban to become applicable. Similar ambiguities are created by not clarifying e.g. whether steriod combinations means only non-sex steroids or sex-steroids also.

Ban of all steroid combinations except for asthma saw no drugs being banned in reality - just a change of indications on paper. (See Table 8.1).

Such ambiguities favour only the drug trade.

It should be the responsibility of the Drug Control Authorities to :

- screen all promotional literature for false information (e.g. recommending Lomotil for children under two years of age),

- monitor prescription guides which are used by doctors (e.g. MIMS & CIMS) to ensure that information contained in these guides is accurate.

- inform health personnel and consumers of the W H O ' s recommendations for an essential drugs list.

- provide information to the general public about drugs which are banned abroad - giving the reasons for their being banned or restricted.

- ensure that proper cautions about side-effects and contra-indications are provided along with the products in the appropriate local language.

- ensure that labelling of products are clear.

- ensure that international non-proprietory names (generic names) are used on all products.

DOUBLE STANDARDS

A growing phenomenon, which is assuming menacing proportions is the manufacture, import, distribution and sale of drugs in India (and other Third World countries) which have either been banned, withdrawn from the market, or heavily restricted in the parent country of the Pharmaecautical Company. In spite of knowing the reasons for the ban abroad, the Company not only continues to sell the product in India, but makes false claims about its safety.

The main reason for such unethical marketing practices is the weakness of legislation in India and the practical absence of a strong administrative machinery.

The menacing proportions of the problem of dumping banned drugs in developing countries caused the Non-aligned Summit to adopt a Resolution (see Tab 2.3) at its meeting in Colombo in 1976.

CONFERENCES, SEMINARS, ETC.

It is well known by now that Pharmaceutical Companies agree to defray the expenses of national and international conferences, seminars and scientific sessions. They host these meetings in the most lavish settings and shower the participants with expensive gifts. Obviously, the burden of these frightful extravaganzas are eventually borne by the poor consumers who have to pay higher prices for dubious products.

On a less visible level, pharmaceutical companies vie with one another to bribe doctors and chemists to promote their products. These incentives take many forms : expensive gifts graded according to the volume of sales, sponsorships for "study tours" abroad, or even straight cash incentives.

The giving of free samples and occasional "give-aways" has become a routine practice.

In contrast to this system adopted by the Government of India, the British Government sends individual notifications to all health institutions and medical practitioners, and gives detailed information about the reasons for a particular drug being withdrawn from the market. (See Table 8.1)

UNETHICAL MARKETING PRACTICES

In the absence of coherent policies, and the even more glaring absence of adequate monitoring and control machinery, India provides a wide-open market for pharmaceutical products. The competition is fierce. The profit-making objective is over-riding. Industry has no inclination or time to consider ethical alternatives. A close look at some of the practices indulged in by the pharmaceutical industry will suffice to show that ethics is the first casualty of competition.

Examples can be adduced by the thousands, but a few are given here only by way of being indicative :

- Glaxo Laboratories cited the authority of 'Lancet' to promote its sales of Ostocalcium B-12, even though there was no such endorsement of the product in Lancet.

- Boehringer-Knoll quoted UNICEF and used their logo to promote the use of streptomycin-chloramphenicol combination for diarrhoea treatment, whereas UNICEF actually promotes simple oral re-hydration therapy for most common diarrhoeas.

- Franco-Indian Laboratories misquoted Goodman and Gilman to promote their tonic, whereas Vitamin B-12 has no role in ordinary anaemia.

- S.G. Chemicals misquoted Goodman and Gilman and Martinadale to promote a combination of two dangerous drugs analgin and oxyphenbutazone, whereas, in fact, the texts warn against the use of this dangerous combination.

Double Standard - Steroid Combination
Before & After the ban

TABLE 8.1

Brand Name	Content	Manufacturer	INDICATIONS	
			MIMS March 1982	MIMS October, 1985
Betaklor	Betamethasone Chlorpheneramine Maleate	Vilco	Allergies of all types	Allergic asthma when Bronchodila-tors alone are ineffective.
Betneton	Betamethazone Chlorpheneramine	Glaxo	Allergy	- do -
Cortina	Dexamethasone Chlorpheneramine	Lupin	Stubborn allergy Food poisoning insect bites.	- do -
Cortopnen	Prednisolone Chlorpheneramine	Uniloids	Allergic Disorders	Allergic Asthma.
Histacort	Chlorpheneramine Prednisolonc	SIRIS	Allergic Manifestation	- do -
Histapred	Prednisolone Chlorpheneramine	Wyeth	Allergic Manifestation	Allergic Asthma when Bronchodilat-ors alone are ineffective.
Kenamina	Triamcinolone	Sarabhai	Allergic disorders angioneurotic oedema Hay fever, drug and serum reactions, certain cases of bronchial asthma	- do -
Perideca	Dexamethozone Cyproheptadine	MSD	Allergic disorders	- do -

Please note the steriods combinations were banned by the Gazette notification July 23, 1983; only allowing steriods combinations for Bronchial Asthma. The differences in the indications before and after the ban to escape the ban is obvious from the above table.

DOUBLE STANDARDS

Multinational companies donot promote many drugs in their own countries or in any developed countries which are marketed in our country and have a sizeable sale. Some them are :-

Name of the Drug.	Company	Country of origin	Indications for which the drugs are promoted
Avil Expectorant	Hoechst	F.R.G.	Cough Expectorant
Soventol Expectorant	Boehirnger Knoll	F.R.G.	-do-
Piriton Expectorant	Glaxo	U.K.	-do-
Periactin	Merind (MSD)	U.S.A.	Appetite Stimulant
Os tocalcium B_{12}	Glaxo	U.K.	Growth Tonic
Amebiotic	Pfizer	U.S.A.	Anti Dirrhoeal
Novalgin	Hoechst	F.R.G.	Pain Killer
Baralgan	Hoechst	F.R.G.	Anti Spasmodic
Suganril	S.G.Chemical (CIBA Giegy)	SWISS	Anti inflamatory Containing phenyl or oxyphenylebutazone

(C/i) Contra-indicated = not recommended

FLAMAR–P **INDOCO**
Oxyphenbutazone 100mg, paracetamol 250mg, diazepam 2.5mg; tabs.
Rheumatic & allied conditions.
10, Rs.3.72
See literature.
Also FLAMAR GRANULES
Oxyphenbutazone 50mg, paracetamol 125mg, dried aluminium hydrox. gel 75mg, mag.trisilicate 50mg; per 5ml.
50ml, Rs.4.22
Below 5 yrs: 2.5 — 5ml twice daily.
Above 5 yrs: 5 — 10ml twice daily.
C/I: Oedema or hypertension. Where there is danger of cardiac decompensation. Renal or hepatic disease. Dyspepsia, peptic ulcer. Blood dyscrasias. Children below 14 yrs. S/P: May potentiate coumarin-type anticoagulants, oral hypoglycaemics & sulphonamides. Check blood regularly.

Source : MIMS India, Jan. 1986.

DEPARTMENT OF HEALTH AND SOCIAL SECURITY
ALEXANDER FLEMING HOUSE
ELEPHANT AND CASTLE LONDON SE1 6BY
TELEPHONE 01-407 5522 EXT
ADDRESS

Our reference
Your reference

To: All Doctors

14 December 1984

Copies To: Family Practitioner Committees
Local Medical Committees
Local Pharmaceutical Committees
Regional Pharmaceutical Officers
District Pharmaceutical Officers

Dear Doctor

LIMITED LIST PRESCRIBING

I am writing to explain the details of the proposals which the Government has recently announced concerning the prescribing of certain medicines under NHS arrangements. In essence the plan is to limit the range of drugs which can be provided under the NHS within the following categories:

cough and cold remedies;

tonics;

laxatives;

analgesics for mild to moderate pain;

antacids;

vitamin preparations;

benzodiazepine tranquillisers and sedatives.

I enclose a provisional list of the drugs to be retained in each category after 1 April 1985. I should stress that this list is provisional and is a basis for the consultations which are now under way with the professions and the pharmaceutical industry. The purpose of these consultations is to identify any additions required to ensure that the final list contains an adequate range of effective generic drugs sufficient to meet all clinical needs.

Some misunderstandings have already arisen. The new provisions will be limited to the categories mentioned above. Reference to any already existing lists, eg specific sections of the British National Formulary, are misleading, as these may contain drugs it is not intended to remove from NHS prescription. Further the provisional list is specifically open to consultation, and we have not yet determined those drugs not to be available. I emphasize specifically that the following classes of medicines will continue to be available:

i. non-steroidal anti-inflammatory preparations, eg ibuprofen;

ii. analgesics used for more severe pain, such as dihydrocodeine tartrate and pentazocine;

iii. enemas;

iv. a range of generic vitamin preparations, including folic acid and B12.

As for the implications of the scheme for prescribing, drugs will either be available on the NHS or not available: there is no intention that doctors will need to indicate the diagnosis or therapeutic category to justify any prescription for a drug remaining on the allowed NHS list.

Nor do the proposals limit the freedom of the profession to prescribe any desired medicine. Doctors will be permitted to prescribe medicines no longer available under the NHS by means of a private prescription. I should add that the majority of these preparations do not in any case require a prescription and can already be obtained by the patient over the counter.

The Secretary of State intends to ask health authorities to apply similar limitations to the use of such drugs in hospitals. He will be laying regulations before Parliament to implement the new arrangements in the Family Practitioner Services in due course.

Before doing so the Secretary of State will welcome the help of doctors to enable him to ensure that the final list contains an adequate range of effective generic drugs sufficient to meet all clinical needs. Comments should be directed to the address below and should arrive by 31 January at latest.

Yours sincerely

Arnold Ackerson

E D ACKERSON
DM FRCP FFCM MFOM
Chief Medical Officer

Reply to: Branch FPS 1A Room 619
Department of Health and Social Security
Eileen House
80/94 Newington Causeway
LONDON
SE1 6EZ

Further copies of this letter may be obtained from CHSS Store, Health Publications Unit, Number 2 Site, Manchester Road, Heywood Lancs, OL10 2PZ quoting date and serial number appearing at right hand top corner.

DRUG INFORMATION AND ETHICAL MARKETING

Drug Information

i) It should be the statutory duty of the drug control authorities to inform health personnel and consumers of the WHO's concept of essential drugs, India's graded essential drug lists, drug policies and their rationale regarding banning of drugs. Rational drug policy as a topic should be included in medical and para-medical education.

ii) Names of the brands banned for manufacture and sales should be widely publicized in medical journals, magazines, national newspapers, giving briefly the explanation and rationale of the ban.

2. Ethical Marketing

i) All sales promotion material including package inserts, medical data sheets by the drug units should be screened by a permanent National Drug Information body, which will be part of the National Drugs and Therapeutics Authority. This body should be responsible for screening as well as ensuring availability of unbiased drug information to the health personnel and consumers.

ii) Use of audio-visuals for sales promotion on drugs to doctors in absence of a printed copy (to be kept with the doctor), of the claims made, should not be allowed.

iii) All drug promotional literature should contain balanced and verified scientific information about indication, contra-indications side effects and drug interaction and antidotes.

iv) Inadequate and inaccurate information in medical promotional literature or package insert or worse still of the total commission of the package insert (as is the trend at present) should be considered a punishable offence.

v) Seminars, scientific sessions held by drug companies to present mainly industry sponsored research studies should be closely monitored and if need, be restricted as it is associated with presentation usually only of favourable results and tend to create a sense of obligation in the minds of certain medical personnel towards drug companies for sponsoring their research.

vi) Sponsoring of National Conventions of professional medical and academic societies by drug industry should be discouraged since consumers have to ultimately indirectly foot the bill and such sponsorship inevitably introduces bias in favour of the company and its products. The health ministry should take up the responsibility for making funds available for such seminars.

vii) Advertisement of tonics and food supplements should not be allowed in the lay-press. OTC sales advertisements making false or misleading or inaccurate claims should be banned. Authorities should ensure that adequate consumer caution is provided to the consumer in regional languages.

viii) Labelling should be clear. International non-proprietory names (generic names) should be used. Consumer caution should be in regional languages.

For food supplements, nutrients, tonics in the consumer caution in regional languages it should be added that "This is not a substitute for normal food" and message given pictorially wherever possible.

ix) "The International Code for Ethical Marketing" as drafted by the Health Action International should be adopted by India.

IX

THE RATIONALITY OF GENERIC NAMES

There are over 60,000 formulations in the country, most doctors prescribe in the range of 60-80 drugs. Unfortunately the choice of these drugs is influenced significantly by marketing practices of the drug companies as has been shown by various studies all over the world.

Use of generic names has a dramatic demystifying value.

The gross differences in prices, in the drug information given the claims made becomes extremely obvious when one is aware that the over 2-3 dozens formulations are basically the same generic product with no significant superiority.

The use of generic names has been recommended by UNCTAD, UNIDO, WHO, HATHI COMMITTEE even the National Health Policy statement of 1983.

The reason why generic names should be used is given below.

ADVANTAGES OF USING GENERIC NAMES

1. Only Generic names are used in medical and pharmacological text books and in pharmacy education.

2. Only Generic names are used in scientific medical journals and WHO publications.

   All purchases of medicines by international tender from international markets are made by generic names.

3. Use of generic names will ensure production, sale and dispensing of more rational single ingredient drugs.

5. It will insure clarity by giving information about the class of drug and thus avoid confusion arising out of many dissimilar brand names of one drug.

6, Quality Drugs are cheaper when purchased under their non-proprietory names than under brand names.

7. Use of non-proprietory names is a valuable aid to memory as it will be easier to learn only selected names and not the names of thousands of brands.

8. Use of generic names will make the selection of Essential drugs and formulations for the national hospital formulary easier.

9. Use of generic names will curtail the heavy promotion of brands, costs of which run into millions, and which are ultimately paid by the consumer. This saving could be used for quality testing or research of new products.

10. Use of Generic names demystifies medicine for consumers and health personnel alike. The fact that several dozen, even hundreds of brands and the generic drugs are therapeutically the same, yet differ amazingly in price is an important awareness.

11. All drugs in the market should be of assured quality. This will remove the excuse to sell branded products of equal quality at exhorbitant prices.

DEMANDS REGARDING GENERIC NAMES

1. Use of Prominent Generic names should be made mandatory in all new and old drugs.

2. All drugs in the market should be quality controlled whether brand or generic.

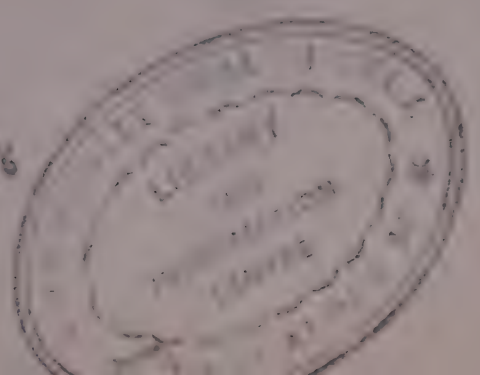
3. Advantages of generic prescribing should be included in medical training on rational therapeutics and aspects of ongoing medical education so as to communicate the rationale to those who could be the potential resisters of the

Regarding Generic case in the Supreme Court - acting support from nationai and international health agencies subscribing to rational drug use and use of generic names should be taken.

BRAND NAMES CAN CAUSE CONFUSION

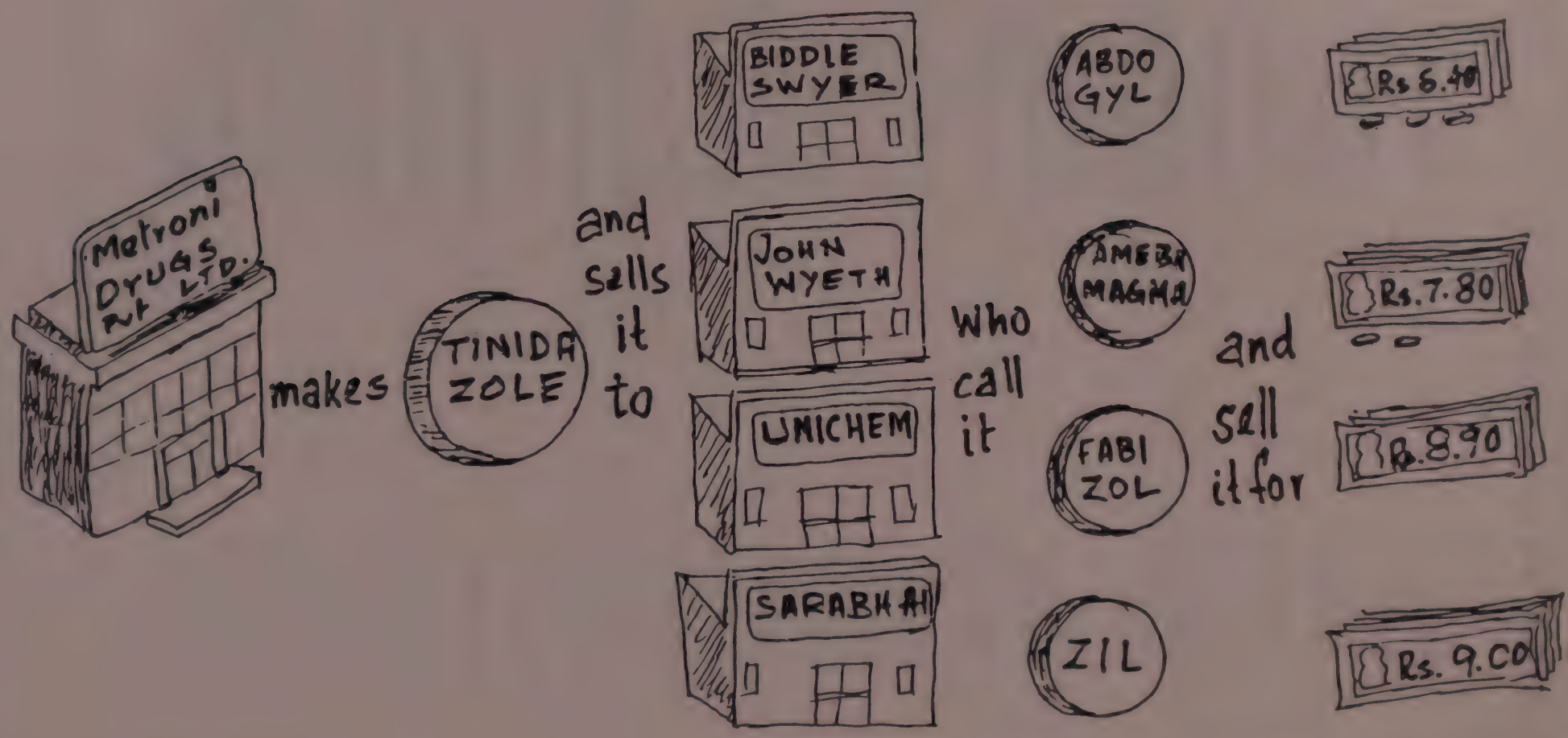
A few examples are given below:

Restin	-	painkiller
Restyl	-	sleeping pill
Restoline	-	antibiotic
Rastinon	-	antidiabetic
Restorem	-	tranquilliser
Restroprim	-	anti-infective
Lasix	-	Di uretic
Laxil	-	Laxative
Amiline	-	psychotropic
Amicline	-	antidiarrhoeal
Celin	-	vitamin
Ciplin	-	anti-infective
Corbutil	-	painkiller
Corbeta	-	anti-hypertensive
Erythrocin	-	antibiotic
Eruthrotone	-	blood tonic
Calcinol	-	Calcium syrup
Calcirol	-	vitamin D_2
Diapen		antibiotic
Diaphen	-	antidiabetic
Disipal	-	anti parkinsonism
Dispeptal	-	digestive enzyme
Cotaryl	-	skin cream
Cortasmyl	-	antiasthmatic
Bitabiotic	-	anti-infective
Bitabiol	-	Vitamin



(Fig 9.1)

WHY WE PAY DIFFERENT PRICES FOR THE SAME DRUG AT THE SAME STORE



X

QUALITY CONTROL

The situation in India, at present, is not only far from satisfactory; it verges on being scandalous. One out of every 5 (20%) drugs is substandard and consequently dangerous or ineffective.

There is official acceptance of the fact that 20% of pharmaceuticals produced in the country are sub-standard and spurious. A survey conducted in 1980 (see Table 10.1) revealed that out of a total of 218 samples collected, 135 sub-standard products were manufactured by 23 multinational companies. This gives the lie to the oft-repeated propaganda that sub-standard drugs are produced in the small scale sector alone; and that the multinationals guarantee high standards of production.

The present machinery to monitor drug production and to test finished products is woefully inadequate. There are only 600 drug inspectors in the whole country, and only five quality control laboratories. Most of these laboratories lack sufficient equipment and manpower to perform their tasks satisfactorily. This is attributed to lack of finances.

With more than 8,000 pharmaceutical units producing around 60,000 drugs of various combinations, it is inconceivable that proper monitoring and enforcement of standards is taking place. The recommended ratio of drug inspectors is one for every twenty five manufacturing units and one for every 100 chemist shops.

By this criterion only the states of Maharashtra, Gujarat and Kerala are reputed to have an adequate drug inspection mechanism.

The facilities to test adverse drug reactions are insignificant. It is no wonder, therefore, that such a large number of hazardous drugs continue to be marketed. The collection of evidence is rendered well-n impossible. This results in barely 10% of convictions of manufacturers of spurious and sub-standard drugs.

Apart from the uncontrolled number of hazardous and irrational drugs being introduced into the market, if we consider the almost explosive increase in the number of sub-standard and adulterated drugs entering the market, the situation is extremely grave. It calls for urgent action.

A rational drug policy cannot fail to make adequate provision for an effective machinery to ensure that legislative and administrative decisions to ensure the safety and well-being of the citizens are implemented.

1. It should be the primary responsibility of the manufacturers to ensure the quality of drug products. However it should be the statutory responsibility of the Drug Control Authorities to monitor the standards and ensure availability of good quality safe and effective drugs. The Government should take all necessary measures to enable the Drug Control authorities to function in an effective manner and discharge the statutory duties cast upon them.

2. The drug control authority should ensure that in a phased manner by the end of 7th 5-year plan the quality control machinery should be streamlined so that only safe quality controlled and quality assured drugs are sold.

3. Regular sample survey of drugs in the market should be done by the Drug Control authorities.

4. Names of brands, batch number, name of pharmaceutical unit concerned in producing sub standard or spurious drugs (if caught) should bve publicised widely to be a deterrent to others and suitable legislation passed for implementation and licenses of offenders withdrawn.

5. Food and Drug courts should be established for expeditious trials with deterring punishments being carried out. Consumer complaints should be confronted quickly and action taken against the erring producers as would be taken on complaint lodged by a drug inspector or someone from drug control authority.

6. Action taken by Drug Control Authorities against erring producers and traders should be made public.

7. Drug legislation to check sales of harmful and substandard drugs should be enforced. Besides punishment, payment of fines and compensation to patients should be enforced to be paid by erring and convicted producers.

8. 1% surcharge on drugs to generate adequate finances for quality control machinery should be introduced.

9. Well equipped labs under the charge of medical colleges, universities, national laboratories should be utilized to provide facilities for testing them. Personnel should be provided the facilities and powers to ensure the above, and also for periodic inspection of sites of chemist & druggist shops and pharmaceutical units.

SUB-STANDARD & SPURIOUS DRUGS

Calcutta THE TELEGRAPH NOVEMBER '85

80% of Indian drugs 'sub-standard'

By A Staff Reporter

BOMBAY, November 1: Nearly 80 per cent of the drugs manufactured in the country were either substandard, toxic or unwanted by the people, a spokesman of the federation of medical and sales representatives' associations of India said today.

BOMBAY Ed., THE TIMES OF INDIA, THURSDAY, MARCH 27, 1986

688 sub-standard drugs sold

By VIDYADHAR DATE

BOMBAY, March 26.

action taken during the last three years against guilty firms.

Corporation is now considering ... of setting up more hospitals and ... research in Bombay. Exec ...

INDIAN EXPRESS, NEW DELHI. 5.2.86

Drug given to patients was 'sub-standard'

Express News Service

BOMBAY, Feb 4.

MADRAS THE HINDU, 18 MARCH '85

Fake drugs getting into Third World

LONDON, March 17:

Growing quantities of fake and potentially lethal antibiotics are being smuggled into the Third World, according to the *Observer* newspaper.

THE HINDU, MADRAS 23.12.85

PM's call for two-pronged attack on drug abuse and spurious drugs

DELHI Financial Express. 28.3.86

Concern over spurious drugs

Our Special Correspondent

DELHI Patriot 15.1.86

Over 10 pc drugs are spurious

Bangalore, Jan 14 (UNI) — Over ten per cent of the drugs being sold in India are spurious, according to Indian Medical Association president V Parameshwara.

23.2.86

State told to root out fake drugs

The States also ought to set up an ... As regards the vast number of ex-... should be ...

Hindustan ...mes Correspondent

NEW DELHI.

INDIAN EXPRESS, NEW DELHI. 25.2.86

States apathetic to spurious drug menace

Express News Service

NEW DELHI, Feb 24.

... the Centre ... set up

Quality Control
- People's right

Times of India
22.4.1986

Triple antigen kills four infants

Sunday Observer
2.2.1986

Death toll rises to 12 in JJ hospital

BOMBAY, Feb 1 (PTI) With the death of two more patients due to suspected contamination of drugs administered to them at the government-run JJ Hospital here, the toll in the drug tragedy rose to 12 today.

Meanwhile, an enquiry panel set up by the Maharashtra government to investigate into the deaths held its first sitting here. Dr. BS Choubey, Dean of Nagpur Medical College, who is heading the panel, told PTI that a preliminary analysis showed drugs such as Glycerol, Manitol and Diamox tablets, which were used in the hospital, were "chemically contaminated".

The histological and chemical reaction of the drugs on the human cells were being analysed in detail and a final report on the cause of the contamination would be submitted to the state government within a week.

The drugs were used in varying quantities for different diseases like brain disfunctions and cataract problems. While they have been withdrawn from use in the hospital, other hospitals have been warned against their use.

condition of two was "stable" in the last couple of days.

The 12 deaths occured during the 11 days from January 20. Doctors started suspecting contamination of drugs when they could not find any other reason for the strange deaths. These doctors suspected adulteration when they found two patients in the ophthalmology department with symptoms not associated normally with the drugs. The effects of the drugs could not be immediately specified as patients with head injuries developed some different symptoms.

Mr Bhirud, has issued an order banning with immediate effect the use of the drug Glycerol.

Quality Control
- People's right

Quality Control
- People's right

Quality Control
- People's right

Quality Control
- People's right

Quality Control
- People's right

Quality Control
- People's right

Quality Control
- People's right

Quality Control
- People's right

MNCs ALWAYS PRODUCE QUALITY PRODUCTS?

REALITY

SUBSTANDARD DRUGS

NAME OF THE COMPANIES	COUNTRY	NO. OF SAMPLES FOUND SUBSTANDARD
BAYER	FRG	13
BOOTS	UK	9
BORROUGHS WELLCOME	UK	8
CIBA GEIGY	SWISS	4
E. MERCK	FRG	2
GLAXO	UK	10
HOECHST	FRG	7
MERIND (MSD)	USA	11
PFIZER	USA	9
ROCHE	SWISS	5

Out of a total 218 cases of substandard production of drugs, 135 samples were from 23 multinationals.

Source : UNI Economic Services Vol.III, No.3,5 January '81.

XI

DRUGS LEGISLATION AND ADMINISTRATION

In order to enable the realization of the objectives of the national drug policy, it is necessary to update existing legislation to make it consistent with the achievement of public health and safety.

India already has several laws in force :

- The Drugs & Cosmetics Act of 1940 as amended in 1955, 1960, 1962, 1964, 1972 & 1982.
- The Drugs & Magic Remedies (Objectionable Advertisement) Act of 1955.
- The Dangerous Drugs Act of 1930.
- The Poisons Act of 1919.

Under the provisions of these Acts, the Central Government has been given powers to ban import and manufacture for sale of such drugs which are therapeutically irrational or which involve risk to human beings or animals.

Rules framed under these Acts also provide for the banning of drugs, the manufacture, sale or distribution of which is prohibited in the country of origin.

However, not withstanding the Laws and the powers acquired by the Government under these Laws, the manufacture, import and sale of therapeutically irrational and hazardous drugs continues unabated.

The implementation of these Laws is frustrated as is evidenced by the few examples given :

A. The Drug Controller of India directed the State Drug Controllers to ban the fixed dose combinations of amidopyrine with effect from February 1982.

When the Maharashtra Drug Controller issued orders for the ban, several multinational drug companies obtained a stay order from the Bombay High Court on the ground that these drugs were allowed to be sold in other States.

B. Through another order, the Drug Controller directed the State Drug Controllers to ban the manufacture of high dose estrogen and progesterone combination from 31 March 1983, and their sales from 30 June 1983 through D.O. No. X19013/8/81-D . Three drug companies which included 2 multinationals obtained stay orders from the High Courts of Calcutta and Bombay on the grounds that the Central Government has no powers to ban the manufacture and sale of the drugs. These stay orders have not yet been vacated. In the meanwhile, the drug continues to be available in the market.

What is so intriguing to the common man is the fact that one of the multinational companies M/s Organon (known in India as Infar (India) Ltd.) is prohibited from manufacturing or selling the product in its parent country, The Netherlands.

Drug Act has since been amended but that has not affected the continued sales of high dose EP drugs which have been legally banned by the Drug Controller long back in 1982.

The end result of the situation is that the Drug Controller of India and the State Drug Controllers are rendered powerless and totally ineffective. The drug manufacturers have challenged the authority of the Government of India to ban their products. They appear to have done this with impunity.

Decisions that should be taken based on rationality of therapeutics by bodies of independent and qualified medical experts are being taken by the Courts with the industry making use of legalistic loopholes.

In drug related matters pertaining to bans of dangerous drugs no stay order should be granted against the larger interest of the public. Moreover it is the responsibility of the Drug Control authorities and the Health authorities to ensure that stay orders such as the one related to EP drugs are vacated as soon as possible. The non-action on their part - which exposes thousands of unborn babies to risk of permanent malformation disability & death - amounts to crime by neglect. Continued sales of dangerous drugs with the support of the courts which are there to ensure justice - is a DOUBLE TRAGEDY.

It is high time that the Government of India reviewed the entire gamut of legislation pertaining to the manufacture, import, distribution and sale of irrational and hazardous drugs. The administrative machinery should be given adequate powers to enforce decisions. As of now the Drug Controllers have been reduced to offering advice instead of enforcing the Law.

OUR DEMANDS REGARDING DRUGS LEGISLATION AND ADMINISTRATION

Drug legislation should provide for the following :

- a system of registration of all medical products (including traditional medicines)
- enforcement of good manufacturing practice
- full control of labelling and advertisement
- control of prices of finished drugs and therapeutic raw materials
- prescription control of toxic/poisonous and habit forming drugs
- summary trial for violations against the drug policy by manufacturers and traders in special drug courts
- heavy penalties including confiscation of equipments and properties for the manufacture and/or selling of spurious and sub-standard drugs.

The legislation should be reviewed, regularly modified and updated in the interest of the public and they should not become bottlenecks for implementation of the national drug policy.

National Drug and Therapeutics Authority

i) The greatest need of the moment is greater public accountability and a greater social control over pharmaceutical industry. For this, setting up an independent machinery such as a National Drug and Therapeutics Authority is imperative, which can scrutinize all the drugs currently marketed in India on an ongoing basis and be held responsible for the nature of drugs in the market. This permanent

body should have representatives with medical, pharmacy and management expertise. Representation being from :

1) drug and health authorities from states
2) Ministry of Chemicals and Fertilizers and Ministry of Finance
3) medical professional and medical academic bodies
4) consumer groups and NGOs involved in health work
5) Trade Unions related to drug industry
6) chemists and druggists.

The Government should establish National Drug Authorities (NDA) at the State level also. The Drug Controllers should be accountable to NDAs.

ii) The recommendations of the National Drugs and Therapeutics Authority should be binding on the drug industry.

iii) Appropriate powers be delegated to Central Drug Controller and State Drug Control Authorities for the proper implementation of the recommentations of the Drug and Therapeutics Authority.

iv) Relationship of NDA with centre and state drug and health authorities should be clearly defined. Its constitution, functioning and powers should be aimed at proper implementation of National Drug Policy. Suitable drug legislation support should be given to this authority so that its decisions are not unnecessarily challenged in the court.

v) Drugs should be dealt with by this NDA rather than by Ministry of Chemicals and Fertilizers, to give greater emphasis to the therapeutic relevance rather than industrial profits and Government's revenue.

XII

DISTRIBUTION OF ESSENTIAL DRUGS

A very important aspect that should find a place in any national drug policy is the effective distribution of essential drugs to the people in remote rural area.

It is generally accepted that only about 25% of the Indian population has access to or can afford modern (Western) medicines. These are people who live mainly in urban areas. The rural population is still largely dependent on traditional systems of medicine and home remedies.

The anomaly in this situation is the fact that while essential drugs for T.B., Leprosy, Malaria and blindness prevention are not available in the peripheral areas, the marketing system is gradually expanding into these areas with useless, irrational and hazardous formulations. Tonics, cough mixtures and tranquilizers are being promoted in areas where people do not have adequate proteins, calories, essential vitamins and minerals in their diets. While the production of pulses, which are the mainstay of the diet of the poor, is decreasing, so-called food supplements like Complan, Bournvita, Protinex etc. are being thrust on the poor who barely manage to exist. They have no food, so the industry provides them with food supplements!! At exhorbitant costs !!!

The sale of tonics in India is 12% as against 3% in developed countries. As against this, the sale of Vitamin A is a mere 3% of all sales of pharmaceutical products. This should give policy makers food for thought.

In a study conducted by UNCTAD in 1977, it was found that 34% of all drugs sold were tonics, tranquillizers and cough mixtures. Anti-microbials were a mere 2% and essential vaccines were 7%.

The problem of getting essential drugs to the rural poor ought to receive special attention within the context of a national drug policy.

Production of essential drugs is not enough. You require an effective system of drug distribution also. From the point of view of the chemists and druggists each item sold is viewed as a potential for profit. The drugs with the higher trade commission are stocked and sold and these happen to be largely the non-essential drugs. The chemists and druggists have already made it clear that as soon as the Government allows a higher mark-up to drug manufacturers, they will expect an increase in their trade commission from 20% to 30%.

Dispensing of drugs by competent chemists is another aspect of the drug which needs attention.

Taking into account the result of the study made by the National Institute of Nutrition, which revealed that 46% of drugs were bought over the counter without proper prescriptions, the role of the chemist/druggist as a prescriber of medicines, and not only as a dispenser, assumes particular significance. Unqualified and untrained chemists and druggists who sell dangerous drugs to ignorant patients can be come a serious social and medical menace.

Thus, we demand a

STREAMLINED DRUG DISTRIBUTION

i) A National Corporation for distribution of drugs and pharmaceuticals to retail drug outlets, hospitals and dispensaries should be established.

ii) National Drugs and Therapeutics Authority (see Section XI) (or its sub-committee) should look into the drug needs of the peripheral health units to identify the bottle-necks and deal with them as a priority and ensure timely drug supply.

iii) This corporation should look into

- requirement estimation of various drugs and their dosage forms;

- purchasing effective, safe and quality drugs at most reasonable costs through bulk purchase and other purchase procedures;

- operating an efficient inventory and stock control system;

- developing an efficient workable system, where drug needs of the peripheral institutions can be a guaged and timely drug supplies ensured.

iv) Adequate drug distribution through the Government's health service infrastructure should be ensured. Essential drugs in adequate quantities and at subsidised rates should be available at PHCs, and their sub-centres.

v) Quality essential drugs should be made available from Government fair-price pharmacy shops. These could be handed over to PHCs and sub-centres.

vi) Education and relevant material on good pharmacy management as produced by WHO should be made available to pharmacy management system.

vii) Trained and qualified pharmacists should dispense drugs.

PRODUCTION AND PRICE CONTROLS

The Indian drug industry comprised of mostly private companies with public sector accounting for just 6% of the formulations market, poses a very special case of production and price controls. Because of the features peculiar to this industry, even the licensing controls which were hitherto used for regulation are just not enough to achieve the objective of essential drugs at reasonable prices. Production controls capable of regulating the producers in terms of the very basket of drugs to be produced are required to be implemented. In the drug industry, the past experience is extremely clearin regard to the use of price controls that without the production controls it will not be at all possible for the government to induce the producers to produce essential drugs merely by the instrument of pricing policy unless it altogether sacrifices the consumer interest which needless to say, has to be given utmost importance as the health of the people is involved. Drugs cannot provide the industry an opportunity for unlimited profit-making is an objective on which hardly anybody can disagree. See Table 13.1.

Drug producers differentiate their products by their brand names and trade marks and compete mainly through the product or promotional competition rather than price competition. Promotional expenditure is an important source of market power in the drug industry. See Table 13.2. Through aggressive sales promotion techniques attempts are made to create the habit among doctors of prescribing brand names. Then there are over-the-counter drugs which are the non-prescription drugs promoted directly to the general public. Backed by vast promotional network the drug companies are capable of distorting the genuine information and pushing the people to consume all kinds of inessential and irrational

drugs. An important feature which needs to be kept in kind in the case of the Indian drug industry is that it is dominated by international companies possessing extremely high market power. For the structure of the industry, see table 13.3. It is our considered opinion that under existing conditions, the instrument of pricing policy by itself is an extremely ineffective weapon to steer the private drug companies to produce the drugs that meet the real medical needs at reasonable prices. The drug companies compete mainly through the product or promotional competition. The profits in the drug industry lie in the mechanisms of sales promotion and in the drugs which can be promoted in larger numbers through the marketing, see table 13.4 and 13.5.

Allowing the market forces uninhibited operations in the drug industry can result in only underproduction of essential drugs, price hike, proliferation of inessentials and more drug disinformation which are already the major problems with this industry.

Thus, in devising the production controls, the point we will have to specially bear in mind today is that :

- the Indian drug industry is flooded with too many of inessentials, useless, irrational and hazardous drugs, and it is

- dominated by a small number of foreign firms possessing extremely high market power, capable of making super profits through transfer pricing, see table 13.6.

Price deregulation, delicensing, broad banding, irrational duty structure which is favourable to the drug imports rather than indigenization and the use of open general license, cannot be the desirable measures to achieve the objective of essential drug production at reasonable

price. The measures which the government is adopting or proposing to adopt, can hardly help in solving the problem of essential drugs production at reasonable prices, the key problem of the Indian drug industry at present. It is our conclusion that the proposed measures are rather capable of doing exactly the opposite to what is needed. This should be a matter of serious concern to all those who are committed to fostering the objectives of rational drug production and technological self-reliance, the cherished goals of the Hathi Committee.

PRICING POLICY WHICH WILL PROTECT THE CONSUMER AND ALSO ENCOURAGE THE NATIONAL SECTOR.

* Cost plus mark-up formula used presently for pricing of the drugs has encouraged inefficient penultimate intermediate based drug production. In the early stages cost plus mark-up formula is alright when the industry is just being established but in the long run as the industry matures such a formula can only be against the consumers' interest. Cost plus formula for those drugs which are being produced, the intermediate or penultimate stage and that too after more than seven to ten years is not only anti-consumer but also anti-national, See table 13.7. A new system of the drug pricing having all the drugs under the span of price controls should be evolved. Such a policy will systematically encourage the goal of efficient drug production, promote national sector and protect the drug consumer, and will prove to be an important answer to the present situation.

* Self-regulation, price controls for a selected few essential drugs, in the absence of any production controls,

can imply only one thing that the government will be encouraging the drug industry to remain inefficient. Inessentials will keep flooding the market as long as the span of price control is confined to only essential drugs. Drug price hike will continue. See table 13.8a. New price controls should encourage generics in the market. This is important because the MNCs through their higher market power have been charging higher prices compared to the National Sector for the same drug. This is true even today in all those market segments where the international companies are dominating. See table 13.8b.

Without taking all the drugs under the span of price controls and canalization of raw material and intermediate imports, the proposal of uniform mark-up made by the international companies and public sector will help much more the international companies only. The MNCs are able to ignore quite effectively the mark-ups ceiling for individual profits through the mechanisms of overpricing of imports and under pricing of exports which contain an element of in-built exaggerated profits. The special provisions regarding price decontrol of new drugs also operate in favour of the MNCs.

The rationale of increased sales promotion cost and trade margin which the industry is giving for the increase in mark-up, if accepted, will legitimise profiteering from the inessentials.

* Increased mark-ups of 65%, 90% and 150% (as reported in National Press as the new pricing formula) can mean only much more burden for the already over-burdened consumers. Higher mark-up for inessentials, it is our view, will encourage only higher production of inessentials.

* Thus, it is our demand that the government should immediately lower the mark-up of inessentials and keep it lower than the essential drugs mark-up. But the government should make no changes in the essential drug price formula on the basis of the NCAER report recommendations as it is a biased report, produced and financed by the OPPI which represents essentially the foreign companies in the Indian drug industry.
Make essential drug price changes only when there is an independent report available on the costing of essential drugs. We also demand that the government should introduce strict price controls for all the essential drugs needed by the people. The priority drugs should be made available at the lowest prices possible. If required, they may even be subsidized for the weaker sections.

BROAD - BANDING
A COUNTER PRODUCTIVE MEASURE

* Broadbanding. It is reported in national press that broabanding is one of the new measures aimed at encouraging the economies of scales in the industry. This can help only the proliferation of

irrational formulations because the measure implies permitting the companies to make by themselves any minor changes in multi-ingredient formulations they like without the change of active ingredient. When already there are too many fixed dose irrational combinations in the market which require elimination, such a measure will do no good.

* Broadbanding cannot imply even any significant economies of scales in the drug industry as in most cases each product has its own technology and needs independent infrastructure and raw material.

* Broadbanding would also lead to more of drug disinformation. Already quite weak quality control would get even further weakened.

Price regulation will become even more difficult because individual drug mark-ups will be more difficult to calculate as the proliferation of drugs in the market will take place in a big way with the proposed new measure of broadbanding. Overall profitability ceilings will have to used as the key price control measure. This measure of overall profitability ceiling is extremely difficult to enforce as the industry is dominated by a small number of international companies capable of resorting to over-invoicing of imports and under-invoicing of exports.

* It is our demand that the government should strictly enforce the following bulk-drug-to-formulation ratios formulated by the 1978 policy:

International companies 1:5 and National Companies 1:10 and gradually make these ratios even more stringent and no broadbanding.

Make international companies to produce formulations only from the bulk drugs produced by them locally inthis country and ensure that they sell 40% of the bulk drugs produced to the non-associated Indian formulators.

DELICENSING A WRONG SOLUTION TO THE PROBLEM OF INCREASE OF ESSENTIAL DRUG PRODUCTION.

Under Production of Essential Drugs.

We said in the beginning that in the drug industry even the licensing controls are not good enough. But to do away with the licensing controls as such will be also wrong. Licensing has special role to play because there does not exist much price competition in this industry and the axe falls on the promotional strategies. Under such conditions if the capacities 3 to 10 times the 7th plan targets have been registered under the schemes of delicensing and DGTD registration, the result can only be under production of many drugs as the measure would increase the investment risk for the producers. See Table 13.9 a&b.

Proliferation of Inessentials

* Delicensing also does not mean automatic increase in production of essential drugs as the impression has gone. This is very well confirmed even by the

industry's recent experience which clearly shows that inspite of the fact that from 1978 atleast 75 drugs out of the 94 delicensed drugs were open for all the sectors to enter into their production, no one in the industry took up the production of essential drugs which are even today totally imported by the country. See table 13.10. We know that rather the drug companies went for the production of new profitable drugs which were not attracting any stringent price controls and where the profits margins were much higher.

Erosion of Self-reliance

* Delicensing of the 94 drugs which cover atleast quite a significant number of drugs that are essentially low priority and inessential drugs in our opinion, can mean also another thing in the present situation, that is the industry will enter now with more freedom into the production of more profitable drugs.

* Delicensing means not only proliferation of the inessentials which guarantee higher profits but also increased control of industry by the international firms which have shown even lesser interest in the essential drug production compared to the national sector. See table 13.11.

* Delicensing may actually even wipe out all those small sector companies which are not tied to the big companies and donot benefit from the arrangements

such as loan licensing, affecting very adversely the nationally accepted objectives of equity, balanced growth, employment and diffusion of skills and technology across the country.

* The multinationals and some other drug companies in organized sector are misusing loan licensing system by floating satellite companies in small scale sector to take advantage of production, licensing and pricing facilities to small scale sector as well as for the purpose of transfer pricing and tax evasion. See table 13.12.

* In quite a few of the market segments, the leaders in drug industry are now the national companies. Delicensing also could mean increased control of the drug market by the international companies which would make price competition further weak. While the foreign companies can gain much heavily from these measures, the consumers will gain nothing. They even may end up paying more than earlier because quite a few of the delicensed drugs happen to fall in the category which attract no price controls (if we go by the recommendations made in the NDPDC report).

* The other measure of liberalization proposed in respect of the international companies, for example, permitting these companies to enter into the formulations based upon new bulk drugs without any linkages to actual production of new bulk drugs if they can satisfy the overall stipulated limit of

bulk drug to formulation ratio parameter of 1:6 mean also further increase in the monopoly control of the international companies on the country's drug industry. Put together all these measures can be only a serious blow to the effort of the Indian companies to indigenize the essential bulk drug technology.

IMPLEMENT LICENSING AND PRODUCTION CONTROLS

* India has technological competence to produce almost all the essential drugs needed for its people. The shortages of essential drugs can only be avoided, if:

  i) It is made compulsory that 75% of the turnover of each manufacturer is from essential drugs and that this should be brought upto 90% in 5 years.

  ii) Incentives are given for production of essential/ priority drugs and deterrent punishment to those producing less than the required quota.

* Make priority drugs already produced in the country from basic stage by the public sector and wholly Indian companies a reserved category. Companies holding foreign equity more than 26% should not be allowed any fresh license for these drugs.

* Cancel all the unutilised capacities of the producers which have been registered for more than one year under the scheme of delicensing and DGTD scheme of registration.

* Take immediate steps to stop the misuse of loan licensing system through appropriate legal , provisions and amending the licensing regulations for this purpose.

WHO SAYS THE DRUG COMPANIES ARE INCURRING LOSSES?

COMPANY-WISE FINANCIAL DATA WITH PROFITABILITY RATIOS FOR SELECTED 30 PHARAMACEUTICAL COMPANIES

Name of Company	Financial year	Total assets	Net Seles	Gross profit	% retun on total capital employed
1. Glaxo Lab.	June '83	93.75	136.17	14.28	14.8
2. Hind. Ciba Gelgy	Dec. '83	62.04	101.18	10.89	14.12
3. Hoechst(I)	Dec. '83	49.70	80.67	9.00	28.25
4. Sandoz (I)	Dec. '83	41.81	63.17	6.56	11.23
5. Alembic	Dec. '83	33.08	56.26	5.99	15.64
6. Pfizer	Nov. '83	37.50	52.08	5.99	15.64
7. May& Baker	Dec. '83	31.29	41.30	5.98	6.67
8. Ranbaxy	Dec. '83	37.53	37.06	3.83	13.58
9. Boots India	Dec. '83	15.18	33.69	3.48	14.21
10. Burroughs	Aug. '83	29.05	32.68	4.55	15.44
11. German Remedies	Dec. '83	20.99	31.77	4.39	22.13
12. Cynamid(I)	Nov. '83	17.76	27.55	4.95	15.55
13. Parke-Davis	Nov. '83	8.85	26.08	2.51	13.14
14. Warner Hindustan	Nov. '83	8.55	25.45	2.53	15.55
15. E.Merck (I)	Dec. '83	18.52	23.18	2.12	19.38
16. Richardson Hind.	June '83	10.18	23.30	3.15	20.21
17. Roche	Dec. '83	15.30	22.30	4.50	28.34
18. CIPLA	Oct. '83	13.14	20.54	1.44	5.42
19. Unichem Lab.	Sep. '83	10.06	19.56	2.04	12.09
20. Abbott Lab.	Nov. '83	7.53	15.28	1.80	14.09
21. Searle (I)	Dec. '83	10.35	13.52	0.92	12.07
22. Boehringer	Apr. '83	6.53	11.35	3.26	29.40
23. Duphar-Int	Dec. '83	7.01	12.49	-0.47	21.25
24. Nicholas Lab	June '83	9.84	11.31	1.29	12.20
25. Fulford (I)	Dec. '83	5.88	9.42	0.64	22.18
26. Jayant Vitamin	June '83	14.81	8.81	1.08	20.44
27. Amrutanjan	Mar. '83	4.25		0.50	21.59
28. J.L. Morson	Dec. '83	4.92	8.52	1.01	17.93
29. Chemo Pharma	June '83	3.09	0.12	0.05	7.93
30. Zandu Pharma	Mar. '83	4.47	4.94	0.50	16.27

Chemical Weekly, March 5, 1985.

SALES PROMOTION EXPENDITURE OF MNC's IN DRUG INDUSTRY

I Comparision of Expenditures on R&D and marketing by 52 MNCs

(Rupees in Lakhs)

Expenditure Head		1975-76 Amount	%	1976-77 Amount	%	1978-79 Amount	%
A.	R&D	107	0.3	136	0.4	156	0.4
B.	Marketing	1317	3.8	1462	3.7	1534	3.6
	Ratio of B A		12		11		10

* M. Bhagat, Aspects of Drug Industry in India. Centre for Education and Documentation, Bombay 1982.

II. MNCs Expenditure on R&D and other Areas*

Outlays on R&D	Approx 0.83%
Outlays on Sales Promotion and Administrative overhead	Approx 33.0%

* Lovraj Kumar committee report, on MNCs which found that this ratio was unduly high in this sector as compared to other industries.

SECTORWISE VALUE OF PRODUCTION OF BULK DRUGS AND FORMULATIONS DURING THE PERIOD 1974-75 TO 1984-85

Sector	74-75	75-76	76-77	77-78	78-79	79-80	80-81	81-82	82-83	83-84	84-85
1	2	3	4	5	6	7	8	9	10	11	
BULK DRUGS											
1. Public Sector	33	43	48	47	49	59	62	67	67	61	
2. Foreign Sector	34	52	63)	105*	56	53	56	72	72	65	
3. Indian Organised)			)								
Private Sector)	23*	25	29)		75	90	95	120	121	155	
4. Small Scale)											
Sector		10	10	12	20	24	27	30	65	74	
Total Bulk Drugs	99	130	150	164	200	226	240	289	325	355	377*
FORMULATIONS											
1. Public Sector	25	35	47	53	60	72					
2. Foreign Sector	203	300	292)	697*	800	778*					
3. Indian Organised)			)								
Private Sector)172*		225*	241)								
4. Small Scale)											
Sector			120	150	190	300					
Total Formulations	400	560	700	900	1050	1150	1200*	1430*	1600*	1760*	1827*

BUSINESS AS USUAL
IRRATIONALS PROLIFERATE

13.4

TOP SELLINGS OF 1984

MOSTLY NON-ESSENTIAL & HAZARDOUS

RANK	DRUG	SALES (Rs.inllacs)	% of MS	Product Group
2	BECOSULES	998	1.0	B.Complex with B_{12}
5	BARALGAN	676	0.7	Anti Spasmdic (Hazardous)
8	DEXORANGE	619	0.6	Blood Tonic
24	HERATOGLOBIN	428	0.4	Blood Tonic
8	VICKS VAPORUB	509	2.6	Non-Drug
20	NOVALGIN	536	0.5	Pain Killer Banned in 15 countries.
12	BENADRYL	524	0.5	Cough Expectorant
24	PHENSEDYL	344	0.3	Cough Syrup
26	MEUROBION	413	0.4	B.Complex
27	OXALGIN	412	0.4	Anti Inflammatory Hazardous
29	SUGANRIL	404	0.4	-do-
31	GLUCOSE-D	399	0.4	Sugar only
38	PROTINEX	366	0.3	Non-Drug
44	DIGEPLEX	314	0.3	Digestive Enzyme Syrup

Source: ORG MAT May'84

* MS=Market Share

BROAD BANDING WILL HELP THEM TO PRODUCE MORE OF THESE NON-ESSENTIALS.

OVER PRODUCTION OF NON-ESSENTIAL DRUGS

13.5

Company	Total Retail Sale in Lakhs	Product	Sale	% of total retail sale
Pfizer	40.65	Becosules Protinex	9.98	32.57%
Hoechst	33.16	Baralgan Novalgin	6.76 5.31	36.40%
Parke Davis	18.90	Benadryl	5.24	27.72%
S.G. Chemicals	17.90	Suganril Oxyphentphenyl butzone Group	4.12	23.02%

Price difference between TNCs and indigenous firms in 1978 and 1982

Generic name of the product	Unit (tablets)	1978 Price of TNC (Rs.)	1978 Price indigenous firm (Rs.)	1978 Price diffefence (%)	1982 Price of TNC (Rs.)	1982 Price of indigenous firm (Rs.)	1982 Price difference (%)
1	2	3	4	5	6	7	8
1. Analgin, 0.5 gm	100	20.34	12.00	69.5	17.80	12.00	48.3
2. Ascorbic Acid, 500mg	10	1.73	0.50	246.0	2.64	0.50	428.0
3. Betamethasone, 0.5 mg	199	29.28 (Pfizer)	17.60	66.4	29.43 (Pfizer)	17.60	67.2
	10	2.51 (Glaxo)	1.76	42.6	1.85 (Glaxo)	1.76	5.1
4. Benzyl Benzoate, 25%	1 litre	28.85	17.77	62.4	28.99	25.00	16.0
5. Chlorpropamide, 100mg	100	9.36	5.70	64.2	9.41	5.70	65.1
6. Chloramphenicol, 250mg	12 cap.	4.09	2.16	89.4	4.16	2.64	57.6
7. Chloroquin Sulphate, 200mg	4	1.03	0.35	194.3	0.93	0.35	165.7
8. Chlopromazine HCl, 25mg	500	33.11	12.00	175.9	42.84	24.65	73.8
9. Diphehydramine HCl, 50mg	50 cap	7.43	3.70	100.8	8.49	3.70	129.4
10. Digoxin, 0.25mg	500	25.73	30.00	-14.2	25.86	36.88	-29.9
11. Diethylcarbamazine, 50mg	1000	65.02	30.00	116.7	63.62	21.05	202.2
12. Diethylcarbamazine Citrate, 50	10	0.70	0.21	233.3	0.68	0.22	209.1
13. Dimethinden Maleate, 1mg	100	8.92	6.00	48.7	8.96	6.00	49.3
14. Glybenclamide, 5mg	500	67.53	69.65	-3.0	67.53	69.90	-3.4
15. Isoniazid 100mg	5000	127.22	110.00	15.7	124.42	110.00	13.1
16. Metronidazole, 200mg	250	65.58	20.00	227.9	64.20	41.25	55.6
17. Methergometrine Maleate, 0.125mg	100	39.77	26.21	51.7	39.96	25.70	55.5
18. Oxytetracycline HCl, 250mg	100 cap	48.49	28.00	73.2	45.45	28.00	62.3
19. Prednisolone, 5mg	1000	179.67	146.37	22.8	180.58	145.20	24.4
20. Paracetamol, 500mg	250	23.29	10.00	132.9	23.41	13.75	70.2
21. Phenobarbitone, 60mg	500	16.58	11.63	42.6	16.66	14.98	11.2
22. Phenytoin Sodium, 100mg	100	6.56	3.52	86.4	6.59	3.52	87.2
23. Sulphaguanidine, 0.5gm	10	1.48	0.79	87.0	1.58	0.79	100.0
24. Sulphadiazine, 0.5gm	10	1.58	0.88	79.5	2.57	2.10	22.4
25. Sulphasomidine, 0.5 gm	250	25.76	17.60	46.4	41.05	17.60	133.2
26. Sulphaphenazole, 0.5gm	250	35.84	33.00	8.6	55.62	33.00	68.5
27. Tolbutamide, 0.5gm	1000	108.76	56.00	94.2	99.86	116.00	-13.9
28. Tetracycline, HCl, 250mg	100 Cap	50.91 (Hoechst)	28.00	81.8	43.00 (Hoechst)	28.00	53.6
	4 Cap	2.05 (Cyanamid)	1.12	83.0	2.01 (Cyanamid)	1.12	79.5
29. Testosterone Propionate, 25mg	10 amps	11.65	3.40	242.6	14.61	3.78	286.5

Source: Indian Pharmaceutical Guide, 1978 and 1982.

Over-pricing of Imports of selected bulk drugs by the TNCs in India

Name of the bulk drugs.	Unit	The price at which the TNCs imported in India (Rs.)	International market a price (Rs.)	Over - pricing b
1.	2.	3.	4.	5.
1. Chlordiazepoxide	Kg	5555	312	1680.4
2. Vitamin B 12	Gram	230	90-100	130-155.5
3, Indomethacin	Kg	3400	360	844.4
4. Prenylamine lactate	Kg	1900	470	304.2
5. Fursam ide	Kg	1650	520	217.3
6. Erythromycin	Kg.	1200	780	53.8

Table 13.7

Formulations Manufactured by the Multinationals from Imported Bulk Drugs.

Name of the Company	No. of Formulations	Types of Formulations marketed
1. Boots	14	Cough lozenses, cold tab., Antacids, Cough Syrup etc.
2. Sandoz	23	Antispasmodic, Ergot, Pain Killers, Vitamins, Antiemitics.
3. Bayer	12	Phenobarbital, Psychtropic Sulphathio Urea, etc.
4. Pfizer	21	Tetracycline, Vitamins, Pencillin, Anticeptic cream.
5. E. Merck	14	Vitamins, Hormones, Cough Syrup.
6. Glaxo	31	Vitamins, Thyroxin, Steroids.
7. Merind (MSD)	7	Psychotropics, Liver extracts.
8. Wyeth Lab	3	Dexamethasone etc.
9. Burroughs Wellcome	20	Anti-Cancer, Antiallergics, Antispasmodics, Cough Syrup, Anti-infective cream.
10.Roche Product	14	Vitamins, Sulpha Drugs, Pain Killers, L-Dopa.
11.Ciba-Geigy	24	Hypotensives, Pain Killer Antiallergics, Anti-spasmodic, coramin, Nasal decongestant, Skin cream.
12. Cyanamid	34	Chlortetracline, Ethambutol, Vitamin, Tonics Haematinics.
13. Eskey Lab (SK&F)	30	Thiazide, Psychotropis Furazolidone, Anti dandruff cream, Iodex.
14. Richardson Hindustan	5	Skin cream, Vitamins, Tonic,Cough Syrup.
15. May & Baker	29	Antillergic, Psychotropic Cough Syrup, Anticeptic cream, Phenobarbitones.
16. Hoechst	6	Digestive Enzyme, Dermatologicals, Vitamins.

PRICE HIKE IN DRUGS

Name of the Drug	Theraputic Group	Company	Max. Retail Price in '74 Rs.	Max. Retail Price in '86, Rs.	% of Increase
Streptonex	Anti TB	Pfizer	Each Vial 0.70	2.77	296
Sodium PAS	Anti TB	Pfizer	100GM 5.62	15.68	180
Protinex	Neutrient	Pfizer	115GM 5.20	13.37	157
Insulin CEG	Antidiabetic	Boots	10m Amp. 5.01	11.10	121
Cadiquin	Antimalarial	Cadila	Each Tab.0.17	0.28	64
Dexorange	Blood Tonic	Francho Indian	280ml. 7.50	16.50	120
Panzynorm	Enzyme	German Remidies	Each Tab.0.20	0.68	240
Triredisal	Vitamin B_1 B_6 B_{12}	Merind	Each Tab.0.14	0.32	129
Reghlor	Chloramphenicol	Sarabhai	Each Cap.0.36	0.57	171
Calpol	Paracetamol	Burroughs	Each Tab.0.07	0.20	186

Table 13.9a

Comparison of Capacities Registered and Seventh Plan Targets for the Seventh Plan Demand Targets of Delicensed Drugs.

Name of the Bulk Drug	Number of Manufacturers who applied under the scheme of delicensing	Capacity already licensed	Capacity registered under the scheme of delicensing	Total	Seventh Plan Targets
1. Aspirin	3	4470 MT	3010 MT	7480 MT	2740 MT
2. Chloroquin	4	616 MT	288 MT	904 MT	470 MT
3. Ampicillin	8	3065 MT	527.6 MT	834.1MT	580 MT
4. Rifampicine	9	NA	275 MT		93 MT
5. Cephalexin	10	NA	310 MT		17.5 MT
6. Methyl Dopa	5	83 MT	291 MT	374 MT	68 MT
7. Diazepem	2	24.78MT	16 MT	40.78 MT	5 MT
8. Pyrazinamide	6	NA	159 MT	--	35 MT
9. Mebendazole	2	20 MT	179MT	174 MT	53 MT
10.Dapsone	2	248 MT	50 MT	298 MT	30 MT
11.Amodiquin	2	125 MT	12 MT	137 MT	47 MT
12. Cephalexin	10	NA	310 MT		175 MT
13. Ibuploofen	12	200 MT	383 MT	633 MT	140 MT

TABLE 13.9b

Non utilisation of capacities registered under DGTD after delution of shares by TNCs

Company	Year	No. of Registration	Utilisation of the registrations
Dupnar Interfran	1980-81	39	18
	1984	8	Nil
Boeringer Knoll	1980-81	6	3
	1981-82	4	Nil
	1983-84	4	4
Reckitt & Colman	1980-81	1	1
	1982-83	6	Nil
	1984	4	Nil
Parke Davis	1983-84	8	Nil

Source: Compiled from the News Letters of India Investment Centre.

BULK DRUGS OPEN FOR ALL SECTORS FOR LICENSING

		1974				1982-83		
	UNIT	NS	MNCs	IMPORTS	NS	MNCs	IMPORTS
RIFAMPICIN	MT	-	-	1.2	-	-	36.9
VITAMIN B6	MU	-	-	27	-	-	57
PANTHENOLS	MT	-	-	14	-	-	62.1
DEXTROPRO POXYPHENE	MT	-	-	N.A.	-	-	8.3
THIABENDAZOLE	MT	-	-	N.A.	-	-	12.6
TETRAMISOLE	MT	-	-	N.A.	-	-	6.2
BETAMFTHAZONE	KG	-	-	-	5.41	583.00	80.66
DEXAMETHASONE	KG	-	-	-	6.25	152.39	437.32
PHTHALYL SULPHATHIAZOLE	MT	-	-	92	9.00	3.98	NIL
SULPHAPHENAZOLE	MT	-	-	2.3	-	55.00	-
TRPROFEN	KG	-	-	8.0	0.05	27.8	25.17
TRIMETHOPRIM	MT	-	-	2.2	24.7	27.2	0.21
RUTIN	MT	-	-	4.3	-	1.51	3535(MU)
FRUSEMIDE	MT	-	-	1	-	4.19	1.5
SULPHASOMIDINE	MT	-	100	10	-	46	-
PHENTRAMINE	MT	NA	NA	NA	-	14.38	1.49
VITAMIN-A	MMU	-	46	-	-	53	20 MT
VITAMIN-D3	KGS	-	88	11	-	180	70
CHLORPHENIRAMINE	MT	-	-	5	-	2	15
PROCAINE	MT	-	34	-	-	34	12
EPHEDRINE	MT	-	9	22	-	2	44408 MU
PREDINISOLONE	MT	-	0.8	-	-	0.8	2

Source : Compiled from government reports.

COMPARATIVE CONTRIBUTION OF MAJOR MNCs 7 NATIONAL SECTOR COMPANIES IN ANTIBIOTICS AND SIMPLE REMEDIES SEGMENTS

	1975			1984		
	TOTAL	ANTIBIO-TICS	SIMPLE REMEDIES	TOTAL	ANTI-BIOTICS	SIMPLE REMEDIES
MNCs(7 TOP CO_s)	82.8	16.9 (20.4%)	23.8 (28.7%)	196.9	18.4 (9.4%)	73.0 (37.1%)
NATIONAL (6 TOP CO)	49.3	29.1 (59.0%)	11.9 (24.0%)	150.2	86.1 (57.3%)	21.4 (14.2%)

Source : Operational Research Group Reports December 1975 and December 1984.

MULTINATIONALS MARKETING PRODUCTS MADE BY SMALL SCALE COMPANIES

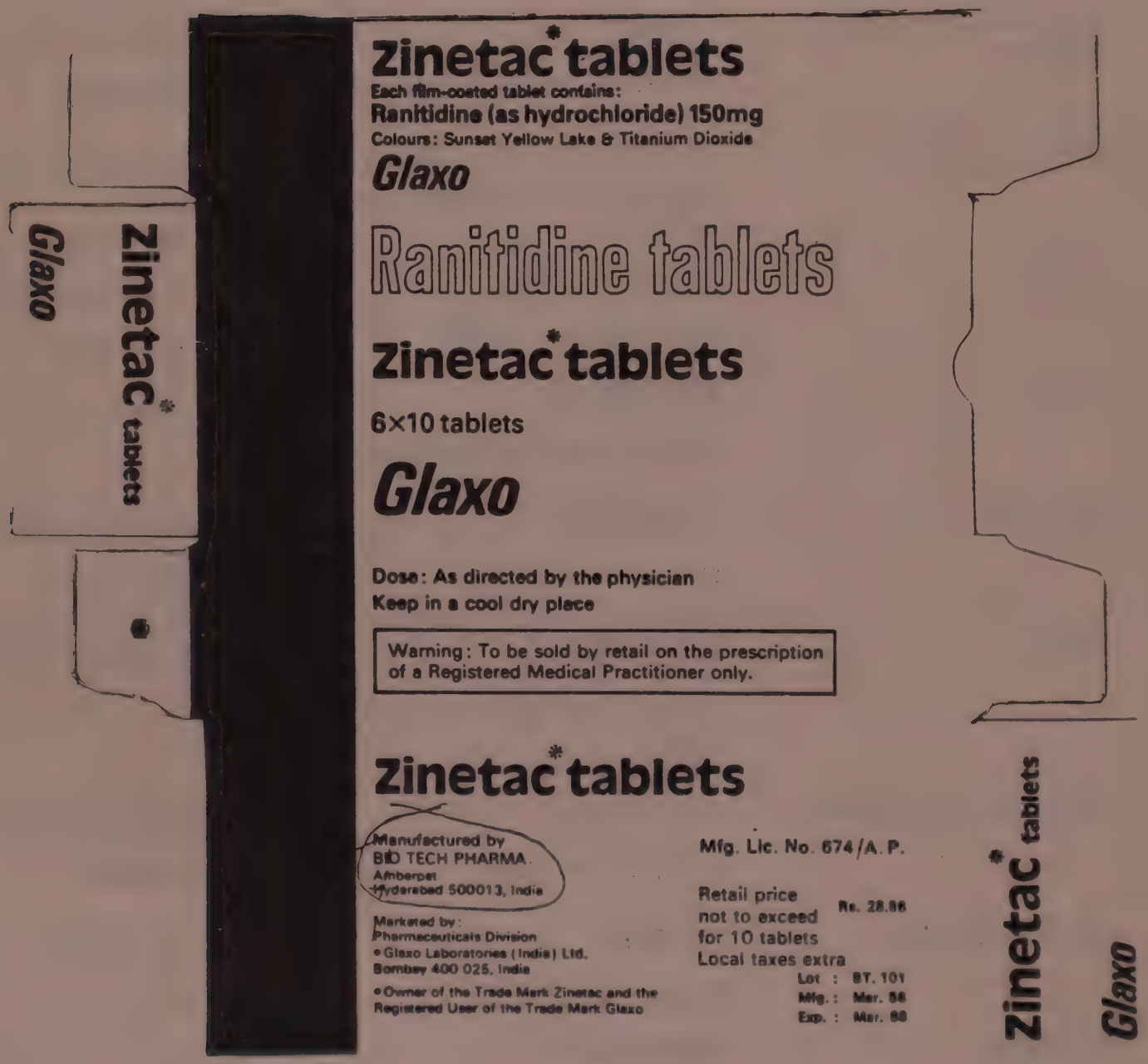
	NAME OF MNCs	BRAND MARKETED	MANUFACTURED BY
1.	GLAXO	PHEXIN (Caphalexin Caps)	CAPSULATION SERVICES. BOMBAY
2.	HOECHST	ALBERCILLIN (Ampicillin Cap)	INGA LABS PVT LTD HYDERABAD
3.	HINDUSTAN CIBA GEIGY	AUBRIL (Trimethoprim Sulphadiazine)	PHARMAPAK PVT LTD BOMBAY
4.	MAY & BAKER	FLAGYL (Benzoyl Metronidazole Oral Suspension (60 ml)	BIODEAL LABS WADHMAN CITY, GUJARAT
5.	-do-	KETROPROFEN (Ketroprofen Cap)	ELEGAN PHARMACEUTICALS BOMBAY
6.	-do-	ANTRIMA (Trimethoprim Sulphadiazine)	-do-
7.	ROUSSEL	CIDOMEX (Amoxicillin Cap)	OPTRED INDIA LTD SRINAGAR
8.	-do-	COMBIFLAM (Ibuprofen & Paracetamol Cap)	CAREWS PHARMA
9.	GERMAN REMEDIES	CATAPRES (Clonodine Tabs)	KOSMOCHEM PVT LTD BOMBAY
10.	US VITAMINS	FENTREX (Ibuprofen Cap)	AMERICAN PRODUCTS CO. LTD., BOMBAY
11.	ETHNOR	PANTEL 200 (Mebendazole Tabs)	NR JET PHARMACALS LTD. BOMBAY

- DPCO-79 - AS NO PRICE APPROVAL REQUIRED FOR SSI UNIT

- NDP-78 - RATIO PARAMETERS OBLIGATION TO PRODUCE BULK DRUGS, CAPACITY LIMITATIONS - SSI UNITS EXEMPT

- IMPORT POLICY - NO QUANTITY CONSTRAINTS

- UNETHICAL TIE - UPS WITH MNCs PRINCIPALS FOR SUPPLY OF BULK DRUG AT PRE-DETERMINED PRICES.



XIV

SELF-RELIANCE AND INDIAN DRUG INDUSTRY

India had allowed operation of drug MNCs in the country, in the hope that they would either bring in scarce capital or bring high technology for production of essential and life saving drugs. However the experience of India, just as those of other countries, shows that neither has been true. Thus,

*Most Drug MNCs brought very little initial capital into the country but they have been remitting large amounts of foreign exchange as profits, royalties and through imports (Table S1)

*Drug MNCs in India were hardly producing any bulk drugs in India till the early sixties.

*When India wanted to establish its own Public sector for bulk drug production, no MNCs from anywhere in the world were prepared to give any technology at almost any cost, whatsoever. India had to then contend with whatever technology it could obtain from a friendly country, USSR.

*It was only with the establishment of Public Sector and the expansion of Indian Private Sector that the MNCs started local production, with most of them restricting their operations mostly to formulations production. They have continued to dominate formulations production (Table S2) and prefer their bulk drug production in the area of non-essentials or low-volume, high-cost drugs (Table S3). They try to further increase their profits through transfer pricing in imports by producing from the intermediate or penultimate stage (Table S4).

*Technology brought in my MNCs has often been to substitute indigenous efforts than to give it any impetus (Table S5) and the imp ort-content of their bulk drug production is usually higher than of their Indian counterparts.

*While they would often not utilize their capacities for essential drugs, they would often overshoot their capacities for non-essential and irrational combinations (Table S6)

*Even now they are not interested to expand their operations into production of essential drugs (Table S7)

*The prices of drugs and formulations marketed by MNCs are normally higher than those of others. While they actually formulate large amounts of bulk-drugs procured from Indian companies, MNCs increase their prices even without approvals (Table S8)

*MNCs expenditure on marketing is in much higher proportions to their R&D expenses (Table S9). While they do not, often concentrate into R&D for developing drugs relevant to Indian conditions, the benefit of their R&D goes directly to their principals abroad.

On the Contrary :

The Indian Public Sector - has concentrated in the area of bulk drug production for a large number of essential drugs. It has also introduced technology for production of a large number of bulk-drugs from a basic stage (Table S10). The public sector has also helped inthe horizontal transfer of technology to others in the Indian sector.

*It is because of the public sector only that the prices of drugs in the country have come down and larger quantities of essential drugs are available.

*The Public sector companies are continuing to expand into production of essential drugs through new industrial licences and letters of intent (Table S7).

*The public sector companies spend a large percentage of their sales turnover on R&D and their R&D has been responsible for developing technology for production of large number of essential drugs.

The Indian Private Sector - has been responsible for initiating Bulk Drug Production and introducing a large number of drugs inthe country.

*It has developed technology for production of a large number of bulk-drugs from basic stage. It has preferentially developed technology for production of essential drugs as compared to those in the foreign sector (TableS11).

*It has consistently increased its share of bulk drugs production and more than doubled its bulk drug production in the last decade itself (Fig.2).

*It continues to expand into area of EDs as well as introduces new drugs which are not being produced by MNCs (Table S7).

*It has not only exported large number of bulk drugs and formulations to many countries but has also exported technological capabilities to other developing countries.

*There are several companies in the Indian Private Sector who spend equivalent amount and percentage of its sales turnover on R&D and has capabilities comparable to those inthe foreign sector (Table S12).

It is therefore important to recognize that MNCs are primarily interested in higher profits through production of non-essential formulations than in production of essential bulk drugs from basic stage, in order to encourage technological inflow.

On the contrary, companies in the Indian Sector, and particularly the Public Sector, has been respo nsible for increased production and availability of essential drugs from basic stage.

It is, therefore, necessary that

a) National Sector, particularly the Public sector should be encouraged to produce more formulations also (of essential drugs).

b) Public sector should be encouraged (through additional R&D support) to develope technology from indigenous efforts.

c) MNCs should be forced to produce only essential bulk drugs and formulations and that within 2 years their bulk drug production should be from a basic stage only.

d) Incentives on R&D should be disaggregated and differential incentives be given to companies in different sector as well as for different nature of R&D. No. incentives should be allowed for research on non-essentials.

WHO SAYS FOREIGN COMPANIES HAVE BEEN DISCRIMINATED ?

Sl. No.	Name of the Company	Expenditure on import of raw materials capital goods and others (Rs. lakhs)			Expenditure on remittance of dividents and others (Rs. lakhs)						Total out flow 1981	Original Equity
					1979		1980		1981			
		1979	1980	1981	Divid-	Others	Divid-	Others	Divid-	Others		
1.	Hoechst	421.95	607.42	383.09	30.99	57.99	45.97	35.98	30.65	110.11	523.85	20.00
2.	Roche	246.33	241.02	180.32	20.03	1.30	20.03	1.30	26.70	1.14	208.16	100.00
3.	Bayer(I) Ltd	845.68	492.01	382.14	49.64	3.90	49.64	3.88	24.82	4.20	411.16	4.00
4.	Ciba Geigy	18.95	590.52	410.34	67.73	28.95	54.18	28.13	54.18	6.24	470.76	2.00
5.	Sandoz	500.01	503.98	684.70	18.11	53.12	18.00	53.20	31.50	61.90	778.10	10.00
6.	Cyanamid(I)	150.41	96.15	102.55	53.35	Nil	56.42	Nil	Nil	Nil	102.55	1.50
7.	E.Merck(I)	67.05	176.98	188.47	Nil	Nil	7.20	Nil	2.01	Nil	190.48	20.00
8.	Glaxo Labs (I) Ltd(Fig. for year ending 30th June)	189.4	268.8	209.8	120.8	Nil	126.9	Nil	139.0	Nil	348.80	1.50
9.	Merck Sharp & Dohme	109.5	147.01	76.19	Nil	Nil	Nil	9.72	Nil	Nil	76.19	180.00
10.	Richardson Hindustan	8.00	13.00	21.00	7.00	Nil	12.00	Nil	15.00	Nil	36.00	0.20
11.	Burroughs Wellcome & Co.	228.38	162.18	244.46	15.00	Nil	22.50	Nil	22.50	Nil	266.96	5.00
12.	Parke Davis	78.50	70.21	77.16	21.00	Nil	14.70	Nil	21.00	Nil	98.16	87.50
13.	Johnson & Jonson (I)	88.22	66.85	75.94	11.54	Nil	11.54		12.15	Nil	88.09	20.00
14.	Pfizer Ltd.	189.56	68.73	97.16	90.75	0.97	124.74	0.85	105.48	0.78	203.42	2.00
15.	Organon(I)	33.03	46.34	47.89	4.30	Nil	4.30	Nil	Yet to be declared			97.54
16.	May & Baker	105.76	190.76	153.60	Nil	0.16	Nil	0.53	65.30	1.01	219.91	N.A.
17.	Warner Hindustan Ltd.	56.10	59.09	52.87	12.90	2.46	10.49	2.55	21.24	3.26	77.37	70.00
18.	Whiffens(I)	Nil	Nil	Nil	0.62	1.62	0.62	1.81	1.2	1.1	2.3	
19.	Boots Co.(I)	180.45	160.41	103.27	14.85	2.27	18.00	2.40	Nil	Nil.	103.27	10.00
20.	Alkali & Chemicals	225.00	205.00	208.00	17.00	27.00	18.00	6.00	29.00	22.0	259.00	35.34
21.	Wyeth Lbs.	37.75 (78-79)	49.01 (79-80)	64.18 (80-81)	11.29 (78-79)	Nil (79-80)	10.99 (80-81)	0.15 (78-79)	11.09 (79-80)	Nil (80-81)	75.27	33.30
22.	Uni-Sankyo	0.52 (78-79)	0.43 (79-80)	5.82 (80-81)	0.52 (78-79)	0.21 (79-80)	0.60 (80-81)	Nil (78-79)	0.73 (79-80)	0.47 (80-81)	7.02	1.00
23.	Eskay Labs. Ltd.(SKF)	55.65 (78-79)	74.67 (79-80)	71.14 (80-81)	7.97* (78-79)	8.87 (79-80)	2.38 (80-81)	8.53 (78-79)	Nil* (79-80)	Nil (80-81)	71.14	N.A.

(Statement of the Ministry in the Loksabha Report of the 82-83 & Hathi Committee)

Who is interested in profiteering?

Sectoral sales of a few drug formulations by anatomical groups

	Anatomical group	Total sales Rs. in crores	Sector-wise Foreign	Percent Indian Private (including JV)	Share Public
1.	Vitamins, andNutrients	122.79	79.30	18.60	2.10
2.	Steroids	29.65	87.66	12.23	-
3.	Cold & Cough Preparations	21.09	74.05	25.83	0.12
4.	Antiparasitics	17.87	67.12	31.46	1.41
5.	Anti-Asthematics	13.41	69. 10	30.88	-
6.	Antidiarrhoeals	12.31	64.68	35.29	0.03
7.	Cardio vasculars	13.68	76.58	20.26	3.17
8.	Opthalmologicals	9.35	68.92	31.08	-
9.	Antacids	7.43	82.95	18.05	-
10.	Anabolics	3.85	87.92	12.08	-
11.	Psycholeptics+ analeptics+CNS	8.18	73.57	25.72	0.71

Source - ORG Retail Store Audit for Pharmaceuticals 1978.

Who controls Indian Formulation Market?

Sector-wise market share of the top 30 companies

Sector	1983		1984		1985	
	No.of Companies	Percent Share	No.of Companies	Percent Share	No.of Companies	Percent Share
Public	1	1.8	1	1.7	1	1.7
Indian	11	24.9	12	24.7	14	26.5
Foreign	13	37.0	17	35.3	15	31.8

Source: O.R.G. Retail Store Audit of June of these years where market share of the Last one year is accounted for.

Produce formulations at whose cost ?
Sector-wise share in Bulk Drugs and Formulations' Production in four Anatomical Groups in 1978.

Therapeutic Group	Percent Contribution		
	Foreign	Indian Private	Public
I. Vitamins :			
Market Share	79.3	18.6	2.1
Bulk Production	7.2	82.3	10.5
II. Antibiotics			
Market Share	38.4	57.8	3.8
Bulk Production	11.0	49.0	40.0
III. Analgesics			
Market Share	46.3	51.3	2.4
Bulk Production	4.0	72.0	24.0
IV. Anti-Parasitic			
Market Share	67.1	31.5	1.4
Bulk Production	37.0	49.0	14.0

(Bulk Drug Production percentage is approximate, since the data for companies wasnot available)

Source: 1. ORG Retail Store Audit 1978
2. Government Reports.

CONTRIBUTION OF A FEW NATIONAL SECTOR COMPANIES AND MNCs IN ANTIBIOTICS AND SIMPLE REMEDIES SEGMENTS

	TOTAL (TRADE SALES) (1984-85)	ANTI-BIOTICS	SIMPLE REMEDIES
National Sector			(RS.IN CRORES)
1. SARABHAI	50.6	34.8 (68.7%)	7.3 (54.5%)
2. ALEMBIC	33.2	18.0 (54.1%)	9.6 (28.8%)
3. RANBAXY	22.8	12.9 (56.4%)	0.6 (2.5%)
4. IDPL	11.9	8.5 (71.3%)	NIL
5. PCI	13.7	7.8 (57.2%)	0.6 (4.5%)
	132.3	82.0 62.0%	18.1 14.0%
- NEARLY 62% CONTRIBUTION IN ANTIBIOTICS-AN AREA OF NATIONAL PRIORITY AND HOSPITAL NEEDS			
Foreign Sector			
1. GLAXO	53.7	0.3 (0.6%)	14.7 (27.4%)
2. PFIZER	37.9	10.0 (26.5%)	14.6 (38.6%)
3. HOECHST	32.8	8.1 (24.7%)	3.3 (10.0%)
4. WARNER HINDUSTAN	16.4	NIL	10.2 (62.1%)
5. RICHARDSON HINDUSTAN	11.9	NIL	11.1 (93.3%)
	152.7	18.4 12%	53.9 35.3%

35% ACTIVITY IN SIMPLE REMEDIES AND ONLY 12% IN ANTIBIOTICS

MOST MNCs NOT INTERESTED IN LOW PROFITABILITY AREAS OF ANTIBIOTICS

MOST OF THE REMAINING ACTIVITY BASED UPON IMPORTED BULK DRUGS AND INTERMEDIATES

Source : Operational Research Group Report December 1984.

MNCs Production of Bulk drugs from intermediate stage and formulations from imported bulk

Name of Co.	No.of Bulk Drugs from Intermediate Stage	No. of Formulations from imported bulk
1. CIBA	12	24
2. Borroughs Wellcome	10	20
3. Hoechst	9	6
4. May & Baker	9	29
5. Suhrid-Geigy	8	NA
6. Bayer	6	12
7. Glaxo	5	31
8. Geoffrey Manners	4	NA
9. Alkali Chemicals	3	NA
10. M.S.D. (Morind)	3	7
11. Cyanamid	NA	34
12. Organon	3	NA
13. Es Kay labs	NA	30
14. Parke-Davis	3	NA
15. Merck	NA	14
16. Roche	3	14
17. Pfizer	1	21
18. Sandoz	1	23
19. Wyeth	1	3

Source : Rajya Sabha unstarred questions No.2255 of 21.3.83 and 2131 of 19.3.84

Technology Imports and MNCs

A. Analysis of 10 Essential Drugs for Impact of Technology Transfer :

i) Foreign Technological imports substituted indigenous efforts, rather than being impetus to Indian Industry.

ii) Indigenous technological activity did not get requisite support.

iii) Indigenous technology was rather overwhelmed by developed technology which was prepared by market with patents and brand names.

iv) Foreign subsidiaries have reluctance in technology transfer for production of basic drugs and rather prefer formulation.

B. Despite increasing participation of Indian Capital, absolute amount of foreign equity participation has increased as a result of :

i) Conversion of reserve funds (e.g. dividends)

ii) Capitalizations of imported machinery and know-how

iii) Purchase of intermediates/raw-materials (transfer pricing)

iv) Trade marks/patent user's rights.

Source : Case studies in technology transfer in pharmaceutical Industry in India CSIR - JNU study, UNCTAD, 1977.

UNAUTHORISED PRODUCTION BY MULTINATIONAL COMPANIES

N A M E	PRODUCT NO.
1. GLAXO	26
2. WARNER HINDUSTAN	21
3. PFIZER	33
4. ABBOTT	2
5. ASTRA-IDL LTD	16
6. WYETH	3
7. GEOFFREY MANNERS	5
8. MERCK, SHARP & DHOME	3
9. CYNAMID	2
10. ROCHE	1
11. HOECHST	4
Total ...	116

MNCs ARE PRODUCING LARGE NUMBER OF FORMULATIONS WITHOUT ANY VALID INDUSTRIAL LICENCE & WITHOUT BOTHERING FOR THE LAWS OF THE LAND.
NO ACTION TAKEN EVEN WHEN THIS UNAUTHORISED PRODUCTION CAME TO LIGHT OVER 10 YEARS AGO.

Source: Rajya Sabha Unstarred Question No.2878 dt.19.12.83
Rajya Sabha Unstarred Question No.2826 dt.22.8.83

Who is interested for Expansion into essential drugs?

Sector-wise analysis of industrial licences in four therapeutic groups during 1979-84

Therapeutic groups/Drugs	Public		Indian Pvt.		Foreign	
	Bulk	Formul	Bulk	Formul	Bulk	Formul
I. Anti-TB						
PAS	-	10Mn	-	-	-	-
INH	15.4T	-	-	-	-	-
PAS+I NH	20T	85Mn	-	-	-	-
Ethambutol	16T	70Mn	112T	15Mn	-	-
Thiacetazone	1.7T	-	-	-	-	-
Streptomycin	171.71	10Mn	175.8T	24.7Mn	-	-
Rifampicin	-	44Mn	0.4T	-	-	-
II. Anthelmintic						
Piperazine	21T	10.3Mn	-	-	-	-
Mebendazole	-	6Mn	47T	-	-	-
Tetramisole	-	2Lakh	0.31	-	0.5T	-
Pyrantel Pamoate	-	-	-	-	30T	-
III. Antimalarial						
Chloroquine (Ph)	-	130Mn	355T	-	100T	-
Primaquine	-	50Mn	0.8T	-	4.5	-
Isosorbide Nitrate	-	-	-	0.5T	-	0.5T
Metraprolol	-	-	50kg	-	-	-
Clonidine						
Hydrochlorothiazide	-	-	0.06T	-	-	10T

UNIDO CLASSIFICATION OF DEVELOPING COUNTRIES ACCORDING TO THEIR DRUG MANUFACTURING STATUS

Group V

Countries which manufacture most intermediates required by the national drug industry and also undertake some local research on new products and manufacturing processes. Asia/India (674, 1973), Latin America/Brazil (474, 1973) Mexico.

Source for UNIDO classification is "The Steps Involved in Establishing a Pharmaceutical Industry in Developing Countries", UNIDO Secretariat.

Do MNCs really spend more on R&D?

Comparision of R&D expenditure of top 10 companies

Sector	R&D Expenditure 1979-80	(Rs. in Lakhs) 1982-83
Public	266.4 (2)	253.63 (4)
Indian Private	521.3	676.44
Foreign Sector	656.7	797.37

Figures in parantheses indicate the number of companies covered.

THE BENEFIT OF R&D BY MNCs GOES MORE TO THEIR PARENT FIRMS

Should MNCs be not persuaded to undertake R&D for drugs in therapeutic groups of priority to India ?

R&D or Marketing Preferences ?

Comparision of Expenditures on R&D and marketing by 52 MNCs

(Rupees in Lakhs)

:penditure ead	1975-76 Amount	%	1976-77 Amount	%	1978-79 Amount	%
. R&D	107	0.3	136	0.4	156	0.4
Marketing	1317	3.8	1462	3.7	1534	3.6
Ratio of B A		12		11		10

M. Bhagat, Aspects of Drug Industry in India. Centre for Education and Documentation, Bombay 1982.

. MNCs Expenditure on R&D and other Areas*

utlays on R&D	Approx 0.83%
utlays on Sales Promotion	Approx 33.0%
ıd Administrative overhead	

Lovraj Kumar committee report, on MNCs which found that this ratio was unduly gh in this sector as compared to other industries.

Who brings in Basic Technology

Sector-wise technological status of bulk-drug production of the top 10 companies in 1978-82

Sector	Basic	Intermediate	Total
Public (4)	39	6	45
Indian Private (10)	25	9	34+7*
Foreign (10)	20	18	38

*Technology available with the small-scale.

Sector-wise Manufacture of Priority Drugs Identified by NDPDC*

Sector	Number of Drugs manufactured
Indian organized	38
FERA	30
Ex-FERA	16
Public	21
Small-Scale	20

* A total of 73 drugs are being manufactured inIndia out of a total of 95 drugs according to the report of the steering committee of National Drugs & Pharmaceutical Development Council, GOI, 1984

WHO HAS BEEN INTERESTED IN DEVELOPING BASIC TECHNOLOGY FOR DELICENCED ESSENTIAL DRUGS?

Sector-wise availability of technology for some of the representative drugs from the delicenced list.

Therapeutic Gp / Drug.	1970				1982			
	Foreign	Public	Indian Pvt.	Small	Foreign	Public	Indian Pvt.	Small
Anti-bacterials								
Tetracycline	✓	✓	✓	-	B	B	B	-
Oxy-tetra	✓	✓	-	-	B	B	-	-
Ampicillin	-	-	-	-	-	I	B	✓
Chloramphenicol	✓	-	✓	-	B	-	I	✓
Erythromycin	-	-	-	-	-	B	B	-
Trimethoprim	-	-	-	-	I	-	B	✓
Sulphamethoxazole	-	✓	-	-	I	B	B	B
S-dimidine	-	✓	-	-	-	B	-	-
Pencillin	-	✓	✓	-	-	B	B	-
Streptomycin	-	✓	✓	-	-	B	B	-
Rifampicin	-	-	-	-	-	B	B	-
Neomycin	-	-	✓	-	-	✓	✓	-
Griseofulvin	-	-		-	-	✓	✓	-
Analgesics	✓	✓	✓	-	✓	✓	B	B
Paracetamol	✓	✓	✓	-	I	B	B	B
Analgin	✓	✓	-	-	I	B	B	B
Ibuprofen	-	-	-	-	B	-	B	-
Antheliminitics								
Mebendazole	-	-	-	-	-	I	B	✓
Piperazine	✓	✓	-	-	-	B	-	✓
Antiameobic								
Metronidazole	✓	-	✓	-	B	B	B	B
Furazolidone	-	-	-	-	-	B	B	-

Therapeutic Gp / Drug.	1970				1982			
	Foreign	Public	Indian Pvt.	Small	Foreign	Public	Indian Pvt.	Small
Anti Malarial								
Chloroquin	✓	-	✓	-	I	B	B	I
Amodiaquin	✓	-	-	-	I	-	B	-
Anti-Leprosy								
Clofazimine	-	-	-	-	-	-	I	-
Dapsone	✓	-	-	-	B	B	-	✓
Anti-TB								
Ethambutol	-	-	-	-	-	-	B	✓
INH	✓	✓	✓	✓	B	B	B	✓
Thiacetazone	✓	✓	✓	-	-	B	B	-
Cardiovascular								
M-DOPA	-	-	-	-	-	I		-
Salbutomol	-	-	-	-	-	-	B	
Frusemide			-	-			-	-
Total (out of 31)	15	13	13	1	15 7B+7I+1	23 16B+3I+4	24 20B+2I+2	15 5B+1I+9

INDIGENOUSLY DEVELOPED TECHNOLOGIES BY NATIONAL SECTOR COMPANIES

1. AMITRIPTYLINE
2. AMOXYCILLIN
3. AMPICILLIN
4. BETAMETHASONE
5. Ca. SENNOSIDE
6. CARBAMAZEPINE
7. CHLORAMPHENICOL
8. CHLORDIAZEPOXIDE
9. CHLORPROPAMIDE
10. CHLOROQUIN PHOSPHATE
11. CIMETIDINE
12. CLOFAZIMINE
13. CLOFIBRATE
14. CLONIDINE
15. CYPROHEPTADINE
16. DEXAMETHASONE
17. DEXTROPROPROPOXYPHENE
18. DIAZEPAM
19. DILOXANIDE FUROATE
20. DIPHENYL HYDANTOIN
21. DOXYCYCLINE
22. EMETINE
23. EPHEDRINE
24. ERYTHROMYCIN
25. ETHAMBUTOL
26. ETHINYL ESTRADIOL
27. FTORAFUR
28. FRUSEMIDE
29. GENTAMYCIN
30. GLYBENCLAMIDE
31. GUAIAPHENSESIN
32. HEPARIN
33. HYDROCHLOROTHIAZIDE
34. HYDROXYZINE
35. IBUPROFEN
36. INDOMETHACIN
37. ISOPROPYLANTIPYRINE
38. LORAZEPAM
39. KANAMYCIN
40. MEBENDAZOLE
41. METHOCARBAMOL
42. METOPROLOL
43. METRONIDAZOLE
44. METHYL DOPA
45. NALIDIXIC ACID
46. NITRAZEPAM
47. NITROFURANTOIN
48. NORETHISTERONE
49. PIRACETAM
50. PROPRANOLOL
51. PVP-IODINE
52. PYRAZINAMIDE
53. QUINIDINE
54. SALBUTAMOL
55. SILVER SULPHADIAZINE
56. SULPHAMETHOXAZOLE
57. SULPHAMOZOLE
58. TERBUTALINE
59. THEOPHYLLINE
60. TINIDAZOLE
61. TRIMETHOPRIM
62. TRIOXSALEN
63. VINBLASTINE
64. VINCRISTINE
65. VITAMIN B_{12}/OTHER VITAMINS

Significant improvement possible due to provisions of Indian Patents Law.

Source: Papers presented at International Symposium on

Public Sector and Technology Generation :

Technological Efforts by the Public Sector and CSIR Labs by 1982

Institution and Achievements	No.of cases
A. I.D.P.L.	
Technology Adaption	
a. Improvements in process	9
b. Alternative/better process	7
Technology Generation	
In Production	22
Successful at Pilot Plant	14
Intermediates	14

B. C.S.I.R. Labs

Name of the Lab	New Drugs	No. of Processes Licenced	No.of Processes in production
1. CDRI	1+2	41	7
2. NCL	0	17	14
3. CECRI	0	7	5
4. RRL Jammu	1	3	2
5. RRL Hyderabad	2	2	2
Total	4+2	70	30

Source :1. Reports of companies
2. Study of CSIR compiled by PTCs, Ahmedabad.
3. Reports of CDRI

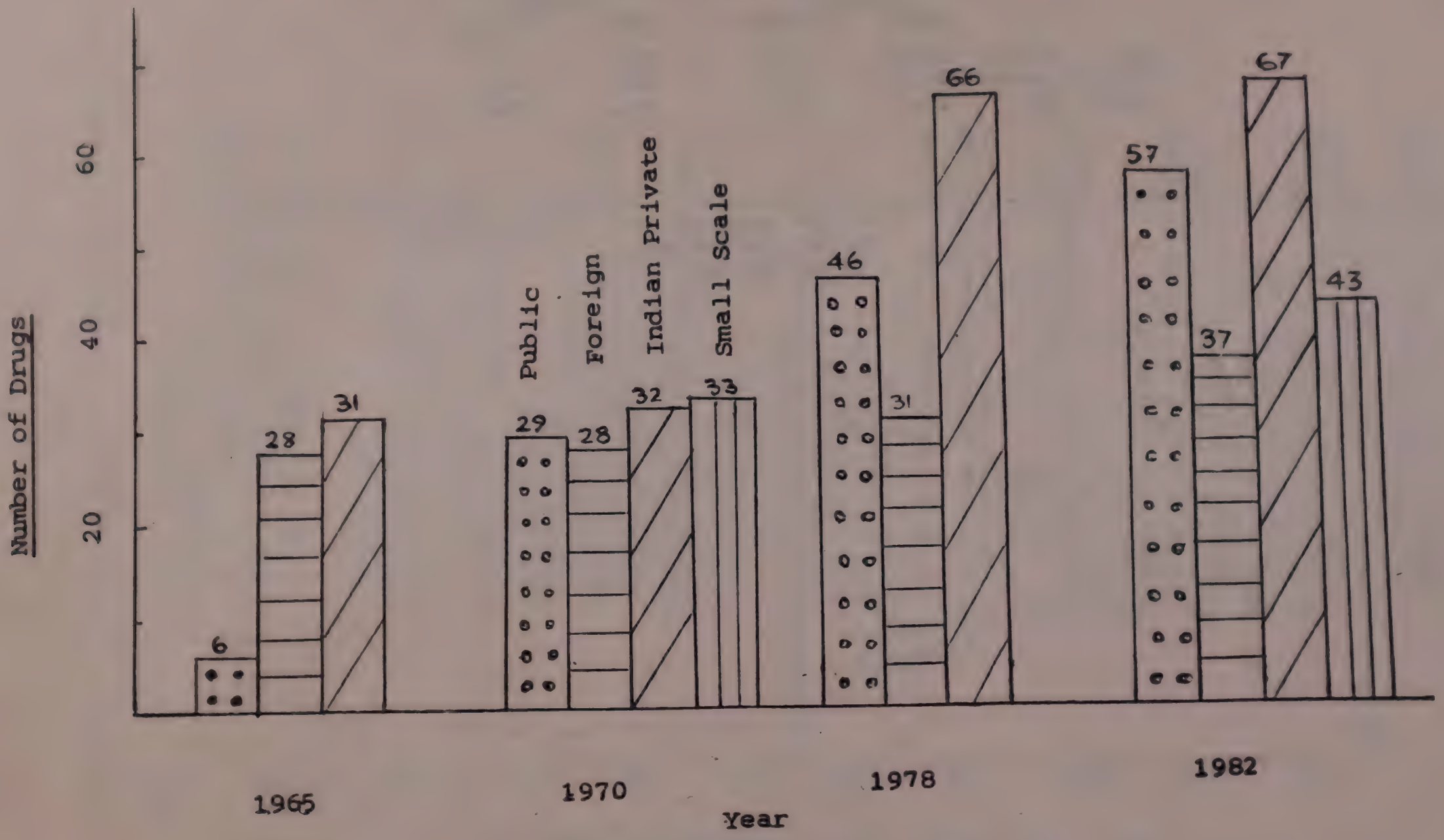
Table S12 : RESEARCH OUTLAYS BY A FEW LEADING NATIONAL COMPANIES AND MNCs

Rs. LAKHS

National Companies		
- AMBALAL SARABHAI	1982-83	347.73
- IDPL	1982-83	174.79
- RANBAXY	1982	120.00
- HAL	1981-82	71.41
- ALEMBIC	1982	68.87
- ATUL	1982	54.82
- UNICHEM	1982-83	45.00
- CIPLA	1982-83	40.00
MNCs		
- HINDUSTAN CIBA	1982-83	266.00
- HOECHST	1982-83	222.00
- PFIZER	1982-83	103.59
- BOOTS	1982-83	102.38
- S K a F	1982-83	96.20
- SANDOZ	1982-83	92.31
- ALKALI a CHEMICALS CORPORATION	1982-83	77.00
- SEARLE	1982	50.81

Source : Lok Sabha Unstarred Question No.3379 dt. 14.8.84

WERE MNCs EVER KEEN ON BRINGING IN TECHNOLOGY ?

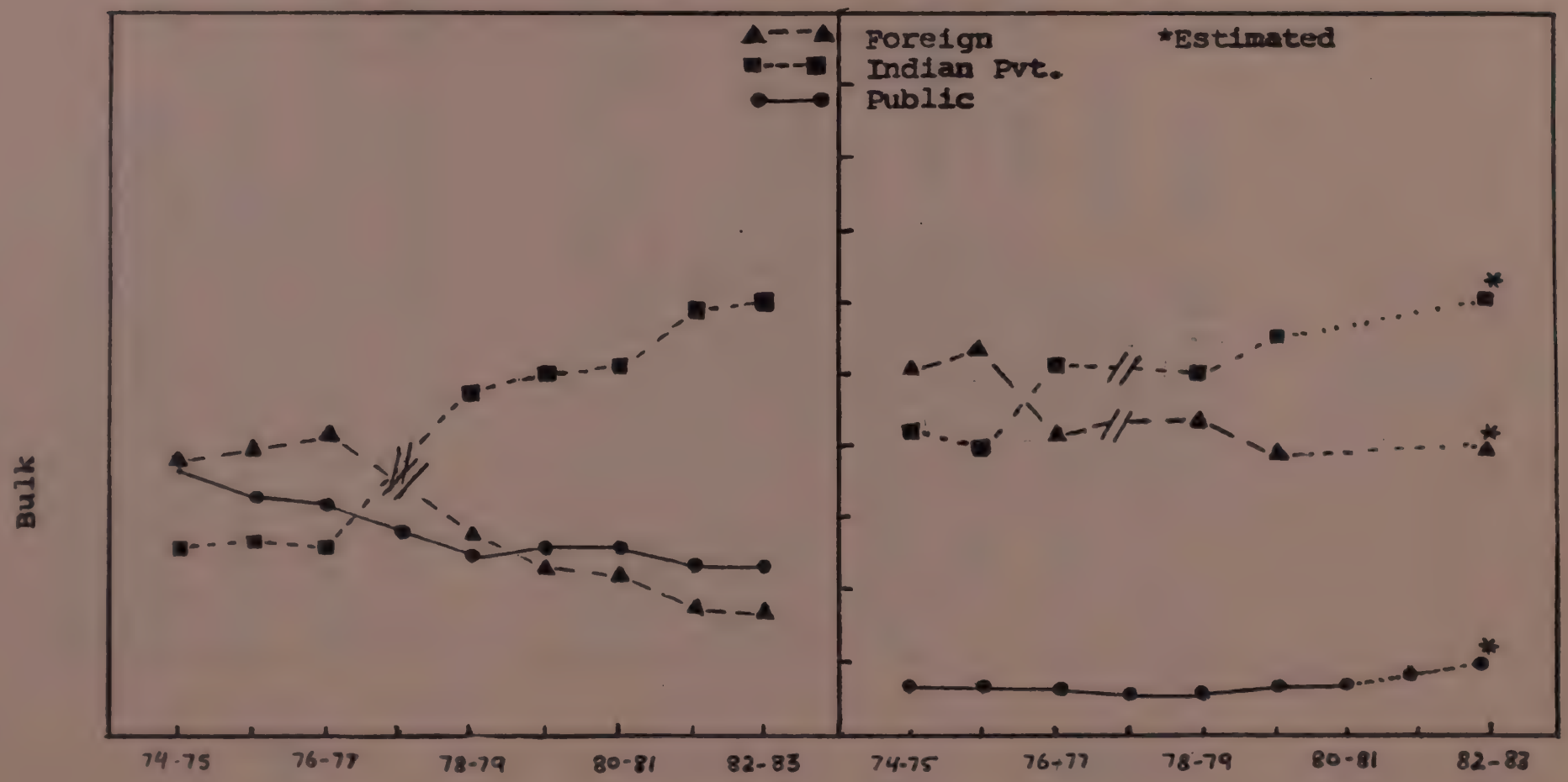


Sector-wise Trend of number of bulk drugs produced by top 10 companies.
(Except Public Sector & Small Scale)

WHO IS INTERESTED IN PRODUCING BULK DRUGS ?

%

	1974-75		1982-83	
	Bulk	Formuln.	Bulk	Formuln.
Public Sector	36.67	6.25	23.1	7.5*
Foreign Sector	38.00	50.75	16.9	39.8
Indian Pvt "	25.4	43.00	60.0	53.0*



Sector-wise value of Drug Production in India (%)

Objectives of the Rational drug policy

We feel that the Rational Drug Policy objectives should include the following :-

A. ASSESSING THE DRUG-NEEDS

1) To identify the drug needs in consonance with the health needs of the people, particularly those required for primary health care; to prepare a graded essential and priority list of drugs for different levels of health expertise inkeeping with actual health needs of the people.

2) To eliminate irrational, useless and hazardous drugs.

B. PRODUCTION, PRICE AND QUALITY CONTROL

1) To make all drugs available at low prices to the people, particularly the essential & priority drugs.

2) To ensure quality control of all drugs.

C. DRUG DISTRIBUTION

To establish a national corporation for the distribution of drugs; retailing of drugs through fair price shops and government's health infrastructures.

D. DRUG INFORMATION AND ETHICAL MARKETING

1) To ensure a drug information system for health personnel and consumers.

2) To ensure ethical marketing.

3) To abolish brand names and introduce generic names for all drugs.

E. SELF - RELIANCE

1) To develop self reliance in drug technology.

2) To foster and encourage the growth of the Indian Sector and to provide a leadership role to the public sector.

3) To aim at quick self sufficiency in the output of drugs with a view to reducing the quantum of imports.

F. RESEARCH AND DEVELOPMENT

To promote research and development for self-reliance and in accordance with the needs of the Indian people.

G. LEGISLATION AND ADMINISTRATION

1) To provide comprehensive drug legislation and administrative support to deal effectively with and implement all the above aims and objectives.

2) To ensure smooth Centre-State relations and inter-departmental coordination for effective and relevant drug production, drug control and drug supply.

H. HUMANPOWER DEVELOPMENT

To fulfill the needs of the above Rational Drug Policy, different type of technical personnel (e.g. druggists, paramedics, etc.) need to be

AIDAN'S MAIN DEMANDS

- Availability of essential and saving drugs
- Withdrawal of hazardous and irrational drugs
- Availability of unbiased drug information
- Adequate quality control and drug control
- Drug legislation reform
- Use of generic names
- Technological Self Reliance

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